William B. Federman
(admitted *pro hac vice*)
FEDERMAN & SHERWOOD
10205 N. Pennsylvania Avenue
Oklahoma City, OK 73120
Telephone: (405) 235-1560
wbf@federmanlaw.com

Lead Counsel for the Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STEVEN MILLER, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. GALENA BIOPHARMA, INC., MARK W. SCHWARTZ, and CHRISTOPHER S. LENTO, Defendants.	Case No.: 2:17-cv-00929-JMV-JBC THIRD AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

Lead Plaintiffs Dan Grunfeld, Shawn Kracht, Joseph Selinger, James Huisman, and Brooks Lieske ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and beliefs are based upon, among other things, Plaintiffs' counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Galena Biopharma, Inc., ("Galena" or the "Company"), with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Galena; (c) review and analysis of transcripts and exhibits from the criminal trial against Dr. Xiulu Ruan and Dr. John Patrick Couch in *USA v. Couch*, No. 1:15-cr-00088-CG-B (S.D. Ala.); (d) interviews with confidential witnesses who are former employees of Galena; and (e) review of other publicly available information concerning Galena.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that acquired Galena's securities from November 3, 2014 through November 9, 2015, inclusive (the "Class Period"), or in the alternative from August 6, 2015 through November 9, 2015, against the Defendants,[1] seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Galena is a biopharmaceutical company that develops hematology and oncology therapeutics. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl). Galena manufactures and markets Abstral in the United States through its commercial organization. As explained by the Company in its SEC filings, Galena "sell[s] Abstral in the United States to wholesale pharmaceutical distributors and retail pharmacies, or our 'customers[.]'"

3. Abstral (fentanyl), a powerful opioid narcotic, is approved by the U.S. Food and Drug Administration ("FDA"), as a sublingual (under the tongue) tablet for the management of

[1] "Defendants" refers to Galena, Mark W. Schwartz, and Christopher S. Lento collectively.

breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. Abstral is a transmucosal immediate release fentanyl ("TIRF") product with product class oversight by the TIRF Risk Evaluation and Mitigation Strategy (REMS) access program implemented by the FDA.

4. During the Class Period, Galena had only two commercial products that were approved by the FDA and could be marketed and sold: Abstral and Zuplenz. However, Galena had no sales of, or revenues from, Zuplenz during the Class Period or at any time, making Abstral Galena's only revenue generating commercial product.

5. Unbeknownst to investors, throughout the Class Period, Defendants were paying kickbacks to the Company's top two prescribers of Abstral (by significant margins) to incentivize them to prescribe the highly addictive medication (often for non-medically necessary purposes). In May 2015, these prescribers were arrested for running a "pill mill" and their practices were shut down.

6. On August 6, 2015, Galena reported sales of $3.38 million from Abstral and an operating loss of $11.3 million for the second quarter ended March 31, 2015, underperforming Wall Street projections. Additionally, Galena announced that full-year revenue from sales of Abstral would be closer to $15 million, which was the low end of the Company's beginning-of-the-year forecast of $15 million to $18 million and about $1 million below what Wall Street was projecting. On this news Galena's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close at $1.51 on August 7, 2015.

7. Then, on November 9, 2015, Galena announced that it had decided to divest its commercial business, that is, Abstral and Zuplenz. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. Galena also reported an $8.1 million

impairment charge to its commercial business net asset group. On this news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015.

8. Following the close of the Class Period, news concerning Galena's Abstral promotional practices, and the federal investigation of those promotional practices, trickled out to the public, including from Galena's SEC filings and from periodic reports concerning the criminal trial and sentencing of the two high-prescribing Abstral doctors.

9. On September 8, 2017, after the close of the Class Period, the United States Department of Justice ("DOJ") announced that it reached an agreement with Galena "to resolve allegations that [Galena] paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral." The settlement resolves a lawsuit filed by a whistleblower under the False Claims Act, which permits private parties to file suit on behalf of the United States and obtain a portion of the government's recovery. As part of the settlement Galena agreed to pay $7.55 million. The DOJ press release stated: '"The conduct alleged by the government and resolved by today's settlement was ***egregious because it incentivized doctors to over-prescribe highly addictive opioids***,' Acting U.S. Attorney Fitzpatrick said." No other information about the government's investigation of, or lawsuits against, Galena was disclosed due to the fact that "the matter remains under seal as to allegations against entities other than Galena."

10. Plaintiffs allege that during the Class Period, Defendants materially misled the investing public concerning the value of Galena's securities. Specifically, Defendants issued materially false or misleading statements that touted the Company's increased Abstral revenues while attributing those revenues to legitimate and legal promotions of Abstral. In truth, however, the Company's revenues were the result of illegal and unsustainable promotional practices, including illegal kickbacks to two disreputable pain doctors who made up ***30% of all Abstral*** sales in the

country and who were overprescribing Abstral in an attempt to earn those illegal kickbacks from Galena.

11. As the concealed risks of Galena's illegal promotional practices materialized—*i.e.*, when the two over-prescribing doctors' practices were shut down and Abstral sales dropped off, and when Galena was then forced to divest its Abstral product line—the artificial inflation in Galena stock dissipated and investors suffered significant damages.

II. JURISDICTION AND VENUE

12. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

15. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

16. Plaintiff Dan Grunfeld, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and

suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

17. Plaintiff Shawn Kracht, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

18. Plaintiff Joseph Selinger, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

19. Plaintiff James Huisman, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

20. Plaintiff Brooks Lieske, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

21. Defendant Galena Biopharma, Inc. is a Delaware corporation headquartered in San Ramon, California. Galena's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the symbol "GALE."

22. Defendant Mark W. Schwartz ("Schwartz") was the President, and CEO of Galena from August 20, 2014, through the end of the Class Period. From 2011 until his appointment as

CEO, Defendant Schwartz served as Executive Vice President and Chief Operating Officer ("COO") for Galena.

23. Defendant Christopher S. Lento ("Lento") was the Senior Vice President of Oncology Commercial Operations at Galena from around May 2013 through December 31, 2015.

24. Defendants Schwartz and Lento, (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of Galena's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers, and investors. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

A. Background of Galena and Its Highly Addictive Drug, Abstral

25. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl) sublingual tablets, a drug designed to address breakthrough cancer pain.

26. Abstral (fentanyl) is an opioid pain medication that is associated with a high risk of addiction and dependence. Fentanyl is reportedly fifty times more potent than heroin and up to 100 times stronger than morphine, making it the most powerful and potentially lethal opioid pain medication available. Fentanyl is among the medications at the epicenter of the growing opioid

epidemic in the United States, which has attracted the attention of United States regulators and other public officials, including former President Barrack Obama and current President Donald Trump.

27. Fentanyl is a major contributor to the alarming number of opioid overdose deaths currently plaguing the nation. For example, as reported in a May 14, 2016 Wall Street Journal article entitled "Hooked: One Family's Ordeal With Fentanyl," in twelve states particularly affected by the opioid epidemic, including New Hampshire, Massachusetts, and Ohio, more than 5,500 people died of fentanyl-related overdoses between 2013 and 2015.

28. Abstral is specifically indicated by the FDA only for "the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Prescriptions written to patients that do not fit this criteria are considered off-label.[2]

29. While doctors are permitted to prescribe a pharmaceutical for a legitimate medical off-label purpose, it is illegal for doctors to prescribe a controlled substance for non-medically necessary purposes.

B. Legal and Regulatory Framework Governing Abstral

1. Federal Anti-Kickback Provisions

30. Galena's marketing practices are subject to federal anti-kickback laws, which prohibit, among other misconduct, offering, paying, or soliciting remuneration to induce the purchasing or ordering (or arranging for the purchase or ordering of) any healthcare item, such as a drug, reimbursable under any federally financed healthcare program, such as Medicare and Medicaid.

[2] Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, 21 U.S.C. § 301, *et seq.*, a drug manufacturer, such as Galena, is prohibited from distributing drugs in interstate commerce for any intended use that the FDA has not approved as safe and effective. 21 U.S.C. § 355 (a) and (b). Thus, it is illegal for drug companies to promote the off-label use of pharmaceuticals. *See* 21 U.S.C. § 355 (a), (b), (d), (j).

31. Specifically, under the Anti-Kickback Statute, ***it is illegal for an individual to knowingly and willfully offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program***. *See* 42 U.S.C. § 1320a-7(b)(2). "Remuneration" refers broadly to anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

32. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure ***proper*** medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thus interfering with the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 309 (proposed Jan. 23, 1989) (codified at 42 C.F.R. pt. 1001).

2. Government's Strict Enforcement of Laws Regulating Opioids

33. The U.S. government strictly enforces laws that regulate the distribution of controlled substances. Such stringent enforcement is necessary in order to counterbalance monetary incentives to increase the distribution of dangerous drugs for non-medical purposes. As such, the U.S. Department of Justice, and state attorneys general, have repeatedly taken legal action against pharmaceutical companies that violate applicable laws. For example, on November 4, 2013, the DOJ issued a press release entitled, "Johnson & Johnson to Pay More than $2.2 Billion to Resolve Criminal and Civil Investigations: Allegations Include Off-Label Marketing and Kickbacks to Doctors and Pharmacists."[3] Coincidentally, the issuance of this DOJ press release on November 4,

[3] The press release is available at: https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

2013 came just as Defendants were beginning to engage in similarly unlawful conduct, as described below.

34. In fact, Defendants were clearly aware of the government's strict enforcement of such laws, as evidenced by the following disclosure in Galena's 2013 Form 10-K, filed on March 17, 2014, just months before the start of the Class Period:

> Our Abstral operations are directly, or indirectly through our customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, federal Sunshine Act, and federal Foreign Corrupt Practices Act. These laws may impact, among other things, our Abstral sales, and marketing and education programs.
>
> ***The federal Anti-Kickback Statue prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing renumeration, directly or indirectly, in exchange for or to induce either the referral of an individual***, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. ***Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving renumeration is to induce referrals of federal health care covered business, the statute has been violated***. ***The Anti-Kickback Statue is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry***. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as a the federal False Claims Act. ***Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only Medicare and Medicaid programs***.
>
> [Emphasis added.]

35. A substantially similar disclosure was included in Galena's 2014 Form 10-K, filed on March 5, 2015—during the middle of the Class Period.

C. Defendants Provided Illegal Kickbacks to Disreputable Doctors to Artificially Inflate Abstral Sales and Revenues

1. Galena's Abstral Sales Were Propped Up By Two Doctors Illegally Prescribing Abstral For Non-Medically Necessary Purposes

36. More than ***thirty percent*** of Galena's Abstral sales were generated by just two pain management doctors, Dr. Xiulu Ruan and Dr. John Patrick Couch, who were convicted of running a pill mill in Mobile, Alabama.[4] The facts alleged in the below paragraphs in this section came directly from information provided by the United States Department of Justice in public releases.

37. Dr. Ruan and Dr. Couch jointly owned and operated two pain management clinics under the name Physicians Pain Specialists of Alabama ("PPSA") as well as C&R Pharmacy, which was co-located with one of the PPSA clinic locations. C&R Pharmacy would only fill prescriptions written by the doctors at PPSA, and Dr. Ruan and Dr. Couch split 75% of the profits that came in from the prescription drug reimbursements. According to the DOJ, approximately 91% of the Abstral prescriptions written by Drs. Ruan and Couch—which cost their patients' insurance anywhere between $1,000 to $24,000 per month—were filled at C&R Pharmacy.

38. PPSA's clinics were raided by law enforcement on May 20, 2015, following an extensive joint investigation by the FBI and DEA. Both doctors were charged with a litany of federal felony offenses, including RICO conspiracy, conspiracy to violate the Controlled Substances Act, substantive drug distribution offenses, conspiracies to commit wire fraud, mail fraud, healthcare fraud, and to violate the federal Anti-Kickback Statute, as well as money laundering. All charges stemmed from the doctors' operation of PPSA and C&R Pharmacy. While no charges were brought against Drs. Ruan or Couch specifically for their relationship with Galena, both doctors were charged with, among others: (1) prescribing controlled substances, including Galena's drug Abstral, "based

[4] Another 10% was generated by Dr. Rho, also a pain management doctor and a "good friend" of Dr. Ruan.

on their own financial interests, rather than the legitimate medical needs of the patients" (*see* Second Superseding Indictment at 15, attached hereto as Exhibit 6); (2) distributing and dispensing fentanyl, including Galena's drug Abstral, "outside the usual course of professional medical practice and not for a legitimate medical purpose" (*id.* at 21); (3) distributing controlled substances, including Galena's Abstral, "for no legitimate medical purpose and outside the usual course of professional practice" (*id.* at 23).[5]

39. During a criminal trial, which lasted from early January to late February 2017, the United States presented evidence that Dr. Ruan and Dr. Couch utilized PPSA and C&R Pharmacy to knowingly and willfully prescribed Schedule II and III Controlled Substances, including fentanyl (with brand names including Abstral), ***outside the usual course of professional practice and not for a legitimate medical purpose***. Of particular importance in the trial were two brand name instant-release fentanyl drugs — Abstral and Subsys. Both Abstral and Subsys are only FDA-indicated for breakthrough cancer pain in opioid-tolerant adult patients. However, evidence showed that Dr. Ruan and Dr. Couch exclusively, or nearly exclusively, prescribed these drugs off-label for neck, back, and joint pain. The United States argued Drs. Ruan and Couch's motives for this illegal prescribing were their own financial self-interests.

40. With regard to Abstral, evidence showed that ***Drs. Ruan and Couch received illegal kickbacks from Galena in exchange for the doctors' prescribing the drug***. The evidence also showed that Dr. Ruan and Dr. Couch purchased more than $1.6 million worth of stock in Galena, the manufacturer of Abstral, and sought to manipulate the stock price by driving up Abstral sales. From the third quarter of 2013 through at least the end of 2014, Dr. Ruan and Dr. Couch were the number

[5] While the Indictment included, as Count Eighteen, charges related to Drs. Ruan and Couch's relationship with Galena, this Count was later dropped and was not presented to the jury. The dismissal of this Count may have been in exchange for Galena' cooperation with the prosecution—cooperation that was discussed in a DOJ press release. *See infra* ¶42.

one and two prescribers of Abstral in the entire United States, prescribing inordinately large amounts of Abstral that far exceeded the prescriptions written by other doctors. During this same time period, ***nearly one out of every three*** Abstral prescriptions written in the U.S. were written by either Dr. Ruan or Dr. Couch for off-label non-cancer pain.

41. After seven weeks of trial, the jury ***convicted*** both doctors of several counts, including conspiracy to prescribe Schedule II and III Controlled Substances outside the usual course of professional practice, conspiracy to prescribe more than 40 grams of fentanyl (***including Abstral***) outside the usual course of professional practice, conspiracy to commit healthcare fraud, and several substantive illegal drug distribution counts related to prescriptions written to particular patients. *See* Verdicts, attached hereto as Exhibit 7 (showing that both doctors were convicted on Counts One, Three, and Eight, which specifically related to the doctors' prescriptions of Abstral).[6] Dr. Ruan and Dr. Couch were sentenced to 252 months and 240 months, respectively.

42. During this time, the DOJ and DNJ had instituted a civil and criminal investigation ***into Galena*** for illegal kickbacks Galena paid to doctors, including Drs. Ruan and Couch, in violation of the Anti-Kickback Statute and False Claims Act. As disclosed in a press release issued by the DOJ on September 8, 2017, the action was settled in exchange for Galena paying more than $7.55 million to the government. The DOJ's September 8, 2017 press release read, in pertinent part, as follows:

> Galena Biopharma Inc. (Galena) will pay more than $7.55 million to resolve allegations under the civil False Claims Act that ***it paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral***, the Department of Justice announced today.
>
> "Given the dangers associated with opioids such as Abstral, it is imperative that prescriptions be based on a patient's medical need rather than a doctor's financial interests," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "The Department of Justice intends to vigorously pursue

[6] In addition, both doctors were convicted of conspiracy to commit mail and wire fraud, and Dr. Ruan was convicted of both conspiracy and substantive money laundering counts.

those who offer and receive illegal inducements that undermine the integrity of government health care programs."

"The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids," said Acting U.S. Attorney William E. Fitzpatrick for the District of New Jersey. "This settlement constitutes another example of the Department of Justice's ongoing efforts to battle the opioid epidemic on every front."

The United States contends that ***Galena paid multiple types of kickbacks to induce doctors to prescribe Abstral***, including providing more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors $5,000, and speakers $6,000, plus expenses, to attend an "advisory board" that was partly planned, and attended, by Galena sales team members and paying approximately $92,000 to a physician-owned pharmacy under a ***performance-based rebate agreement to induce the owners to prescribe Abstral.*** The United States also contends that ***Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral.*** Galena has not marketed any pharmaceutical drug since the end of 2015.

Two of the doctors who received remuneration from Galena were tried, convicted and later sentenced to prison in the U.S. District Court for the Southern District of Alabama following a jury trial of, among other counts, ***offenses relating to their prescriptions of Abstral. Galena cooperated in that prosecution***.

***

The settlement is the result of a coordinated effort by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the District of New Jersey, with assistance from the Department of Health and Human Services Office of Counsel to the Inspector General, and the Food and Drug Administration Office of Criminal Investigations' Metro Washington Field Office.

[Emphasis added.]

43. The DOJ also brought charges against former officers of Insys Therapeutics, Inc., the manufacturer of Subsys, for illegal kickbacks the company paid to doctors in exchange for writing prescriptions of Subsys.

2. Evidence Presented During the Criminal Trial Against Drs. Ruan and Couch Demonstrate that Defendants Knowingly Paid Illegal Kickbacks to Doctors

44. Evidence presented during the criminal trial against Drs. Ruan and Couch demonstrates that during the Class Period, Defendants Lento and Schwartz were paying illegal kickbacks to Drs. Ruan and Couch to increase the doctors' prescriptions of Abstral. Defendants

Schwartz and Lento paid these illegal kickbacks despite knowing since at least October 2013 that Drs. Ruan and Couch treated few, if any, cancer patients but that these doctor's prescriptions of Abstral were higher than other doctors by huge and inordinate margins.

a. Galena'a "RELIEF" Registry

45. According to evidence and testimony presented at the criminal trial of Drs. Ruan and Couch, Galena created and maintained a "RELIEF" registry/program that Galena launched in July 31, 2013. According to Galena's "fact sheet" for the registry, the name RELIEF stands for "Rapid Evaluation of Lifestyle, Independence, and Elimination of Breakthrough Cancer Pain with Freedom." *See* Exhibit 2 (attached hereto). The program was purportedly designed to be an "[o]bservational patient registry study as indicated for the management of breakthrough pain (BTcP) in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." *Id.* Conveniently, the program also paid doctors $500 for every Abstral patient the doctors enrolled in the RELIEF registry. *On paper*, the RELIEF program was only available to a "patient prescribed Abstral for BTcP [breakthrough cancer pain]."[7] *Id.* Importantly, however, David Corin ("Corin") (Galena's National Sales Director) unequivocally testified that *in application*, Galena knowingly used the RELIEF program for prescriptions to treat non-cancer pain in patients who did not even have cancer. Indeed, Mr. Corin's sworn testimony is clear:

Q: Who were the patients that could qualify for the RELIEF Program?

A: Cancer and noncancer patients.

46. ***Defendants Lento and Schwartz*** knew that the RELIEF program was operating to pay doctors for Abstral prescriptions. According to emails from October 2013 between Defendant

[7] While the term BTcP is used in Galena's literature, the abbreviation BTcP to stand for breakthrough cancer pain is well known in the industry. *See e.g.* https://www.ncbi.nlm.nih.gov/pubmed/29875184.

Lento and Dr. Ruan—emails that were copied to Defendant Schwartz, Allan Valmonte (Galena's Director of Clinical Affairs), and David Rowan (Galena's Regional Business Director)—Defendant Lento promoted the RELIEF program to Dr. Ruan. *See* Exhibit 3 (attached hereto). Indeed, the emails reflect that Galena's sales representative Jeff Palmer had pitched the RELIEF program to Dr. Ruan and that Dr. Ruan had expressed "interest" in the program; however, when Dr. Ruan was sent the information for the RELIEF program, he did not think he had qualifying patients—because the documentation suggested that it applied only to cancer patients with breakthrough cancer pain. *See id.*[8] (explaining that Dr. Ruan initially "was under the impression that the candidates for the study would be patients with non-malignant pain" but he later thought (after reviewing the documentation) that the RELIEF program only applied to cancer patients for which his "practice does not have very many patients who qualify," *i.e.*, does not have many cancer patients). In response to the email explaining that Dr. Ruan did not think he had patients that could participate in the RELIEF program, Defendant Lento, coping and referring to Defendant Schwartz, corrected Dr. Ruan and tried to persuade Dr. Ruan to prescribe Abstral to his non-cancer patients and to enroll them in the illegal RELIEF program, saying:

> I hope all is well. I was surprised to receive this note today (via Neil). I had thought that you were very excited to participate in Galena's RELIEF Registry. ***I believe there might exist some confusion on patient eligibility.*** Would it be possible to discuss at your earliest convenience?
>
> I'm copying ***Mark Schwartz***, (Galena COO), and Allan Valmonte, (Director of Clinical Affairs), and Dave Corin (Regional Business Director).
>
> Thank you for your consideration.

[8] The emails reflect that Galena was partially working through Sunbelt Research Group, LLC, to get Dr. Ruan to participate in the RELIEF program. Research indicates that Sunbelt Research Group, LLC is/was classified as a "pharmaceutical preparations company."

Exhibit 3 at p. 1 (emphasis added). Indeed, as David Corin later testified, Dr. Ruan misunderstood the program's eligibility because Galena's RELIEF program actually enrolled both "cancer and non-cancer patients."

47. While Dr. Ruan ultimately chose not to participate in Galena's RELIEF program (out of concern that he would not be able to freely trade his Galena stock), Dr. Couch ***did*** participate in Galena's RELIEF program and received several payments from Galena for his Abstral prescriptions to non-cancer patients. In fact, while Galena's RELIEF program was originally designed to have a limit so that a doctor could only enroll a maximum of 25 patients on the RELIEF program, "the ***parameters were changed where Dr. Couch was allowed to enroll up to 75 patients***" in the RELIEF program, according to David Corin's testimony. In addition, David Corin testified that while the RELIEF program was also originally designed to pay the doctor $500 per patient, Dr. Couch was allowed to request payment of "***up to $2,500 per patient***." Thus, Defendants not only paid kickbacks to Dr. Couch for his "enrollment" of non-cancer patients in the RELIEF program but even changed the program's parameters to allow Dr. Couch to receive more kickbacks and at apparently higher payments.

48. It is clear that Defendants implemented and maintained the RELIEF program to knowingly pay doctors for their Abstral prescriptions, in violation of the Anti-Kickback Statute. Unsurprisingly then, in the DOJ press release announcing its settlement with Galena, the DOJ and DNJ specifically took aim at the RELIEF program, describing it as an obvious kickback, saying: "Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral."

b. Galena's Rebate Agreement

49. David Corin (Galena's National Sales Director) testified that Galena had rebate agreements with several dispensing clinics. According to Corin, under the rebate agreements, Galena was to pay the dispensing clinics a percentage, generally ranging from 8.75% to 20%, of the prescription dollars the clinic/pharmacy sold in a given month.[9] This, again, is a classic example of a kickback.

50. On October 1, 2014, Galena entered into such a rebate agreement with C&R pharmacy, the pharmacy owned by Drs. Couch and Ruan. As Corin testified, in 2014, "the company and C&R Pharmacy [Dr. Couch and Dr. Ruan's pharmacy] partnered on a marketing services agreement," which was "also known as the rebate agreement." The prosecution entered the marketing services/rebate agreement into evidence, and as Corin testified, the rebate agreement was signed by ***Defendant Schwartz*** on behalf of Galena and was executed on October 1, 2014. *See* attached hereto Exhibit 4 (rebate agreement). Under the rebate agreement, Galena would pay C&R Pharmacy a certain percentage, between 8.75% and 20%, for the prescriptions of Abstral the pharmacy sold in a month. Corin said that he was aware that Drs. Couch and Ruan owned C&R Pharmacy. As Justin Palmer (nurse practitioner at PPSA) testified, "C&R [the pharmacy owned by Drs. Couch and Ruan] was part of PPSA, at least in my mind, and it was connected to the building." Mr. Palmer further testified that the PPSA patients essentially always got their Abstral prescriptions filled at C&R Pharmacy, connected to the PPSA clinic, due to the fact that Abstral "was such an expensive drug, that nobody else really carried it and we did."

51. As Corin explained, "[t]he average prescription [of Abstral] could be several thousand dollars. For the higher doses, you can get into the $10,000 range." Press releases from the DOJ have

[9] Indeed, Mr. Corin, explained that the rebate agreements would essentially be the same as the one Galena entered into with C&R pharmacy: "the only difference is it's C&R."

similarly explained that Abstral costs a patients' insurance anywhere from $1,000.00 to $24,000.00 per month. Accordingly, the 8.75% to 20% kickback available to C&R, pursuant to the rebate agreement, was a significant incentive to Drs. Ruan and Couch to write more prescriptions of Abstral (regardless of medical need).

52. Corin testified that "when this agreement went into place, C&R Pharmacy would earn more money from filling Abstral prescriptions." And the rebate agreement ***did*** provide more money to Drs. Ruan and Couch, as evidenced by a Federal Reserve document that the prosecution entered into evidence, which reflected a February 18, 2015 wire in the amount of ***$97,924*** from Galena to C&R Pharmacy's Wells Fargo bank account. FBI agent Amy White testified that the FBI believed the $97,924 wire to be a payment pursuant to the rebate agreement.

53. Corin testified that the rebate agreement was, in fact, made "in order to add additional profit to C&R's prescrib[ing] or dispensing of Abstral." In other words, Galena entered into the rebate agreement with C&R Pharmacy to incentivize Drs. Couch and Ruan to write more prescriptions for Abstral.

54. Specifically, the testimony of David Corin indicates that Galena entered into the rebate agreement with the doctors in order to increase Drs. Ruan and Couch's Abstral prescriptions following a drop in the doctors' prescription rate. Indeed, while Drs. Ruan and Couch were consistently the top prescribers of Abstral, the number of prescriptions Drs. Ruan and Couch wrote had decreased beginning in early 2014. According to Corin, Galena largely attributed the decreased prescriptions[10] to a change to how the Company's voucher program was applied to Drs. Ruan and Couch:

> Q: What, if anything, did Galena Biopharma attribute the dropoff in Dr. Ruan and Dr. Couch to during that time period, from quarter one to quarter two?

[10] Mr. Corin also testified that the drop-off in Abstral prescriptions from Drs. Ruan and Couch coincided with an insider trading scandal at Galena that was made public in or around February 2014 and which upset Drs. Ruan and Couch because it negatively affected their Galena stock holdings.

A: The change in rules that we put into the voucher program.

Q: And by and large, as you reviewed this document [attached hereto as Exhibit 5] previously, did you see similar massive drop-offs for a lot of other doctors from first to second quarter?

A: No.

55. According to testimony from David Corin, since the time Galena began marketing Abstral, it had a voucher program that permitted new Abstral patients to receive certain initial prescriptions of Abstral for free. Corin testified that Galena's voucher program allowed new Abstral patients to "get up to three prescriptions of Abstral at 32 tablets apiece, so up to 96 tablets of Abstral free of charge while that patient worked to get to the right dosage to treat their cancer pain." Conveniently, the voucher program also paid the pharmacy that filled the prescription 8.75 percent of the prescription amount as a "service fee." As Corin testified, "[s]o we pay the pharmacy 8.75 percent for a voucher to initiate the patient." Corin explained that for non-voucher "maintenance" prescriptions (*i.e.*, prescriptions for patients already taking Abstral), the pharmacy would ***not*** receive the 8.75 percent "service fee."

56. As Corin also testified, Galena initially permitted Dr. Ruan and Couch to use all three vouchers (for a total of 96 tablets of Abstral) at once, but Galena stopped allowing this in March 2014. As Corin testified:

Q: Did Dr. Ruan and Dr. Couch abide by the way the voucher program was supposed to work?

A: ***They -- they used it differently***.

Q: How did they -- how did Dr. Ruan and Dr. Couch use the voucher program?

A: ***All three prescriptions would be written at once.***

Q: Why is that different than what you described as the way it was supposed to work?

A: Because the titration model didn't fall into place, so the dose was pre-selected for all three prescriptions.

***

Q: Was there a change – you mentioned that a change was made to the voucher program?

A: Yes.

Q: When was that change made?

A: In March of 2014.

Q: Why was that change made?

A: ***Because we were losing money on the voucher program***.

57. Following the March 2014 change to Galena's voucher program, Drs. Ruan and Couch "couldn't write three vouchers at once," according to Corin:

Q: When the voucher program changed, did it affect the way that pharmacies were reimbursed for Abstral?

A: For the voucher fee?

Q: Yes.

A: Well, it would only affect it in that they couldn't write three vouchers at one.

Q: ***And is that what Dr. Ruan and Dr. Couch had been doing at that time?***

A: ***Yes, for the most part.***

In other words, after March 2014, Drs. Ruan and Couch could not as readily access the 8.75 percent "service fee" that C&R had been receiving under the voucher program.

58. Thus, the rebate agreement was executed with Dr. Ruan and Couch's C&R Pharmacy to get Drs. Ruan and Couch's prescriptions back up following the change to how Galena permitted C&R to use its Abstral vouchers. Indeed, Corin testified that he made a trip to Mobile on September

24, 2014 to visit with Drs. Ruan and Couch to try to come to an arrangement with Drs. Ruan and Couch. As Corin testified:

Q: What was the purpose of this trip?

A: Again, ***Dr. Ruan was very upset with the company and wanted to understand – although he was upset, wanted to find ways to work with the company too***.

***

Q: What, if anything, did Dr. Ruan suggest be done during this meeting?

A: He suggested that the company work with the pharmacy to find a better way to procure Abstral.

Q: And when you say "work with the pharmacy," which pharmacy are you talking about?

A: C&R.

Q: And procure Abstral, what do you mean work with C&R for a better way to procure Abstral?

A: The concern was that the pharmacy was currently losing money prescribing the product for maintenance scripts.

Q: And are the maintenance scripts, are those the full-month scripts, not voucher scripts?

A: Yes. Yes.

Q: ***What, if anything, did Dr. Ruan suggest be done?***

A: ***He suggested that the company talk to the pharmacy and the -- and to find a way to partner up.***

Q: And by "partner up" what do you mean?

A: Find a way to make sure the pharmacy wasn't losing money.

59. The solution was the rebate agreement, which was signed days later. The rebate agreement achieved its intended purpose of driving up Abstral prescriptions and Galena revenues, as Mr. Corin admitted that the number of prescriptions for Abstral from Dr. Ruan and Dr. Couch increased after the rebate agreement went into effect:

A: It went into place right here and around October 1st, 2014.

Q: After that time period, after it went into place, do you know from working at Galena whether or not prescriptions form Abstral from Dr. Ruan and Dr. Couch increased?

A: ***They did increase***.

60. This increase was reflected in an internal Galena document emailed on February 5, 2015 by David Corin to Galena sales representatives, including a confidential witness ("CW") who was a Territory Business Manager for Galena from August 2014 through August 2015.[11] The document emailed by Corin, and copied to ***Defendant Lento***, on February 5, 2015 shows that the amount of Abstral prescriptions written by Drs. Ruan and Couch notably increased after the rebate agreement was executed, in the following material numbers:

	Aug. 2014	Sept. 2014	Oct. 2014	Nov. 2014	Dec. 2014	Jan. 2015
Dr. Ruan	$101,172	$147,421	**$150,683**	**$245,783**	**$230,887**	**$163,638**
Dr. Couch	$96,590	$98,706	**$188,934**	**$228,631**	**$212,827**	**$157,064**

61. Thus, in comparing the two months ***before*** the rebate agreement and the two months ***after*** the rebate agreement, we see that Dr. Ruan wrote a total of $248,593 (for August and September) versus a total of $476,670 (for November and December), and Dr. Couch wrote a total of $195,296 (for August and September) versus a total of $441,458 (for November and December). *See also* Exhibit 5 (chart of Drs. Ruan and Couch's Abstral prescriptions showing a significant uptick in prescriptions around October 2014).[12] Accordingly, the rebate agreement had a material impact to Galena, particularly since the Company's total previous ***quarterly*** revenues were in the range of

[11] The internal Galena document was provided to Plaintiffs' Counsel by CW.
[12] The chart was presented as evidence in their criminal trial of Drs. Ruan and Couch. The writing on the chart was made by counsel for the U.S. Attorneys' Office.

around $1 million to $2.3 million. *See infra* ¶¶82, 85, 88 (comparing net revenues to the previous year's revenues). Indeed, based on the above information, Dr. Ruan's prescriptions created $627,353 in revenue for the fourth quarter of 2014, and Dr. Couch's prescriptions created $630,392 in revenue for the fourth quarter of 2014, making a combined total of ***$1,257,745*** in revenue for 2014 Q4 just from these two doctors. That amounts to ***more than half*** of any quarterly revenue the Company had reported by this time.

62. Moreover, Drs. Ruan and Couch's prescriptions under the rebate agreement ***were being paid for***, unlike the prescriptions they had written under the voucher program (which, according to Corin, made up the majority of Drs. Ruan and Couch's prescriptions prior to March 2014), for which Galena had to provide free of charge. As such, Drs. Ruan and Couch post-rebate agreement prescriptions created significantly more revenue for Galena. Indeed, Galena announced its "***strongest Abstral quarter to date"*** as the fourth quarter of 2014—the quarter that started with the signing of the rebate agreement. *See infra* ¶82. And Galena continued to report revenue numbers that were ***consistently materially higher*** than Galena's revenue numbers in 2013 and early 2014 (when Drs. Ruan and Couch had been prescribing massive amounts of Abstral but when most those prescriptions were provided at the expense of Galena under the voucher program), with Galena announcing for the first quarter 2015 its "***second-highest quarter of net revenues since our relaunch of Abstral in 2013***" (¶85), and announcing for the second quarter of 2015 Galena's new ***"strongest net revenue quarter to date***" (¶88). Specifically, as set forth *infra*, ***after*** entering into the rebate agreement with Drs. Ruan and Couch, Galena reported revenue of: (1) "$3.2 million in the fourth quarter of 2014 and $9.3 million for the year ended December 31, 2014, compared to $1.3 million and $2.5 million, respectively, for the same periods of 2013" (¶82); (2) "$2.8 million in the first quarter of 2015, ***a 28% increase*** compared to $2.2 million for the same period a year ago" (¶85); and (3) "$3.4 million in the second quarter of 2015, ***a 48% increase*** compared to $2.3 million reported

for the same period in 2014[.]" ¶88. It is, indeed, reasonably inferable that the prescriptions by Drs. Ruan and Couch in 2015 were predominantly responsible for these revenue numbers given that following the government raid and shutdown of Drs. Ruan and Couch's PPSA clinic in May 2015, Galena was unable to even continue manufacturing and selling Abstral.

63. By providing percentage payments to C&R Pharmacy (owned by Drs. Couch and Ruan) for the prescriptions of Abstral filled there, Galena was paying Drs. Ruan and Couch for the prescriptions of Abstral they wrote—the definition of a kickback. Accordingly, the DOJ would later allege in a lawsuit filed in the District of New Jersey that the rebate agreement operated to provide illegal kickbacks.[13] *See supra*.

c. Defendants' Repeated Interactions with the Doctors

64. Evidence presented at the criminal trial of Drs. Ruan and Couch demonstrate that Defendants Schwartz and Lento, along with other Galena representatives, frequently communicated with Drs. Ruan and Couch and even traveled to Mobile for promotional visits with the two doctors.

65. For example, according to an email between ***Defendant Lento*** and Dr. Ruan by December 5, 2013, the two had "discussed in [] previous conversations" the opportunity for Dr. Ruan to be "involved with Galena at the highest advisory/consultatory level."[14] Other evidence showed that ***Defendant Lento***, along with David Corin (National Director of Sales) and Jeff Palmer (Galena's

[13] Because Defendants entered into the rebate agreement with Drs. Ruan and Couch's pharmacy after Defendants Lento and Schwarz had been specifically told by Dr. Ruan that PPSA treated few, if any, cancer patients, the rebate agreement was not only an illegal kickback, it also constituted off-label promotion of a drug for an unindicated purpose.

[14] Dr. Couch attended at least one of Galena's Advisory Board Meetings, for which, according to the US Department of Justice, Galena paid Dr. Couch $5,000 plus expenses. According to other emails presented during the trial, Dr. Ruan ultimately decided not to attend Galena's Advisory Board Meeting due to concerns that he might hear inside information that would prevent him from trading his Galena stock, since he and Dr. Couch "plan[ned] to sell quick on the side." Dr. Ruan explained this reasoning in a January 18, 2014 email to Dr. Couch, adding "[m]aybe I'm just paranoid, but since [sic] we both have purchased some stocks and we use their products more than others."

sales representative), took a trip to Mobile on February 25, 2014 to visit with Drs. Ruan and Couch who were upset with the Company because the stock price had dropped significantly after certain Galena insiders made massive stock sales—actions that became the subject of a Cease and Desist Order by the SEC.[15] David Corin explained that he knew Drs. Ruan and Couch were upset about the insider sales because "[t]hey sent several emails to my boss, whose name was ***Chris Lento***, and others in the organization. And I was—I had been forwarded those messages."

66. Other testimony and evidence showed that, at the behest of ***Defendant Schwartz***, Corin made several other trips to Mobile immediately prior to and during the Class Period to visit Drs. Ruan and Couch, including trips on September 24, 2014, January 20, 2015, and April 21, 2015. According to Corin, "[Schwartz] wanted us [Galena representatives] to be more consistent in how often we came" to visit Drs. Ruan and Couch. Corin explained that "[Schwartz] wanted us to have a more regular cadence in our visits" to Drs. Ruan and Couch "[b]ecause other companies were visiting consistently and the higher-ups in those companies, as well – from CEOs to most C-level employees. It was important that we had a presence as well." Corin confirmed that other companies, including Insys, sent their CEOs and other high-level people to meet with Dr. Ruan and Dr. Couch,

[15] Galena's former CEO Mark Ahn, CFO Ryan Dunlap, and Senior VP of Investor Relations Remy Bernarda were themselves defendants in an earlier securities fraud action, *In re Galena Biopharma, Inc. Sec. Litig.*, No. 3:14-cv-367-SI (D. Or.), which alleged that Galena and certain of its officers and directors committed a classic "pump and dump" manipulation scheme, whereby they paid third-party newsletter writers to post articles touting Galena stock. The articles, which purported to be authored by credible investment professionals, never disclosed that they were paid promotions, and Galena never disclosed the Company was using such stock promoters that on their face appeared to be independent. As a result of the third-party promotions, Galena's stock price nearly quadrupled, and Galena insiders quickly sold almost all their stock, reaping approximately $16 million in personal profits. The parties reached a settlement of these claims. On April 10, 2017, the SEC announced it had reached a settlement with Galena for charges the SEC had brought stemming from this stock manipulation scheme. As part of the SEC settlement, Galena and its former CEO, Defendant Ahn, agreed to cease and desist from future securities laws violations, and Ahn was prohibited from acting as an officer or director of any registered issuer of securities. Defendant Ahn agreed to disgorge $677,250, pay prejudgment interest of $67,181, and a civil penalty of $600,000. Galena agreed to pay a civil penalty of $200,000.

and that this was part of "what prompted more meetings or the need for more regular meetings [with Drs. Ruan and Couch] from executives at Galena." Corin explained that Dr. Ruan "made clear that we weren't giving them the same attention that other customer – other companies were." Corin elaborated that "[h]e [Dr. Ruan] explained it very clearly that we weren't doing enough. As a business, we weren't listening to them [Dr. Ruan and Dr. Couch] enough and we weren't going to be successful."

67. ***Defendant Schwartz***, Galena's CEO, also made at least two trips to Mobile during the Class Period to visit with Drs. Ruan and Couch during the Class Period: one trip in November 2014 and one trip in February 2015. David Corin explained that Defendant Schwartz made these trips to Mobile "[b]ecause Dr. Ruan and Dr. Couch wanted to meet with him [Schwartz]." According to Corin, "[i]t was demanded by Dr. Ruan that he [Schwartz] meet with him [Ruan]."

68. Defendants also actively sought to help Drs. Ruan and Couch get prior authorizations for their non-medically necessary Abstral prescriptions (resulting from illegal kickbacks), including David Corin's January 20, 2015 trip to Mobile to "introduce Dr. Ruan and Dr. Couch to Steven Brennan" who "was responsible for [Galena's] GPS program, which was our prior authorization program."

69. Such promotions and incentives were undoubtedly due to the fact that Drs. Ruan and Couch prescribed such large amounts of Abstral. As Corin testified, Drs. Ruan and Couch were "important individuals for Galena":

> Q: Were Dr. Ruan and Dr. Couch important clients or important individuals for Galena Biopharma?
>
> A: Yes.
>
> ***
>
> Q: ***Why were Dr. Ruan and Dr. Couch important to Galena Biopharma?***
>
> A: ***Because they were our highest Abstral prescribers.***

Q: ***And was it highest by a large margin?***

A: **Yes**.

70. To be sure, Defendants' frequent trips and meetings with Drs. Ruan and Couch (as well as the kickbacks paid by Galena to Drs. Ruan and Couch pursuant to the rebate agreement and the RELIEF Program for which Dr. Couch participated, discussed *supra*) were intended to keep the doctors prescribing extremely large amounts of Abstral.

3. Defendants Knew Drs. Ruan and Couch Were Overprescribing Abstral for Non-Medically Necessary Purposes

71. Throughout the Class Period, Defendants were aware that Drs. Ruan and Couch were the two largest Abstral prescribers by huge and inordinate margins. Indeed, just these two doctors accounted for approximately 30% of all Abstral sales in the county. *See* Exhibit 1, attached hereto.

72. According to Corin's testimony, Galena kept "an internal document that [Galena] would send out on a quarterly basis with all of our prescribers in the country, how many prescriptions they had written each quarter." The internal Galena document showed that from third quarter 2013 through fourth quarter 2014, ***Dr. Ruan wrote 1,302 prescriptions*** for Abstral, and ***Dr. Couch wrote 649 prescriptions*** for Abstral. As David Corin (Galena's National Sales Director) testified, the only doctor "in the ballpark with" Drs. Ruan and Couch was Dr. Rho—another "pain management doctor" who was a known shareholder of Galena and who also predominately treated, and prescribed Abstral to, non-cancer patients—who ***wrote 611 prescriptions*** for Abstral. *See* Exhibit 1. By comparison, ***the next highest prescriber*** of Abstral (*i.e.*, the fourth highest Abstral prescriber in the country) during that same period ***wrote only 153 prescriptions*** for Abstral. *Id.* In other words, Dr. Ruan wrote ***851%*** more Abstral prescriptions than the fourth highest prescriber of Abstral in the country, and Dr. Couch wrote ***424%*** more Abstral prescriptions than the fourth highest prescriber in the country.

73. Indeed, as demonstrated in Exhibits 1 and 5 (attached hereto), Dr. Ruan and Dr. Couch went from writing essentially no prescriptions of Abstral to writing copious amounts of Abstral over the course of just a few months. *Id.* The amount of Abstral prescriptions suddenly being written by Drs. Ruan and Couch was notably inordinate not only to their prior lack of such prescriptions but also compared to the number of prescriptions written by other doctors. *See* Exhibit 1. Both of these facts were readily observable to Defendants, as they kept track of each doctors' prescriptions of Abstral, as evidenced by Exhibit 1 (the internal Galena document) and as further evidenced by the document provided by CW, which listed doctors' Abstral prescriptions in dollar amount by month. *See also, infra*, ¶78, (Lento describing Galena's "internal metrics" that Defendants were "monitoring" and "keeping track of," including daily sales, average prescription price, number of prescribers" for Abstral).

74. It is almost impossible to imagine that Defendants did not know, in the absence of extreme recklessness, that these doctors were overprescribing Abstral for non-legitimate purposes. Such an astronomical number of sudden Abstral prescriptions by these two doctors—who had already told Defendants point blank that they treated very few, if any, appropriately indicated patients—simply could not be explained as anything *other* than the overprescribing of a highly addictive and dangerous drug for non-medically necessary purposes.

75. To be sure, Drs. Ruan and Couch were convicted of prescribing Abstral for non-medically necessary purposes outside the usual course of professional practice. As, Justin Palmer (a nurse practioner at PPS) testified that PPSA "didn't have many cancer patients," and for the entire period "from 2011 to 2015," he had seen maybe "10 or 15 active cancer patients." Bridgette Parker, another nurse practitioner at PPSA from 2012 until its shutdown in May 2015, further testified that she thought the off-label uses for which Dr. Ruan and Dr. Couch prescribed Abstral were inappropriate, saying "I felt that it was used often when it shouldn't be." Ms. Parker also confirmed

that both Dr. Ruan and Dr. Couch "asked" or "encouraged" her to prescribe Abstral to patients even when there did not appear to be a need for it or when the patients said their current prescriptions "were working okay."

4. Defendants Knew That Abstral Sales Were Artificially Inflated and Unsustainable

76. Eventually, the illegal practices of Drs. Ruan and Couch in overprescribing and dispensing Abstral were brought to an end. The shutdown of Drs. Ruan and Couch's "pill mill" also marked the end of Galena's Abstral division. As David Corin testified:

Q: Do you know what, if anything, occurred in ***late May of 2015*** regarding Dr. Ruan and Dr. Couch?

A: ***Our understanding is that their practice was shut down.***

Q: Following the shutdown of their practice, what happened to prescriptions for Abstral?

A: In regards to Dr. Ruan and Dr. Couch?

Q: In regard to overall number of prescriptions written for Abstral after Dr. Ruan and Dr. Couch's practice was shut down?

A: ***Our volume dropped.***

Q: Did it drop by a little bit or did it drop significantly?

A: ***Significantly***.

Q: What then happened to Galena's ability to promote Abstral?

A: We were limited because ***we couldn't make up that revenue***. And eventually Galena was forced to sell the product in December of 2015.

***

Q: At what point did you leave Galena?

A: December 31st, 2015.

Q: Did you leave on your own or were you fired?

A: The commercial team was dissolved.

Q: Why was the commercial team dissolved?

A: There were no commercial products to sell.

Q: And is that after Abstral was sold off?

A: Abstral and Zuplenz, which was our other product.

77. Defendants knew, or should have known in the absence of extreme recklessness, that Abstral sales were largely supported by two pain management doctors prescribing inordinately large amounts of Abstral to non-cancer patients, and that these sales were unsustainable given the government's aggressive oversight of prescription opioids.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS VIOLATED SECTIONS 10(B) AND 20(A) OF THE EXCHANGE ACT AND SEC RULE 10B-5

A. Defendants' Materially False or Misleading Statements

1. November 3, 2014 and November 5, 2014 Statements

78. The Class Period begins on November 3, 2014. On November 3, 2014 and November 5, 2014, Defendants reported Galena's third quarter 2014 results and, in doing so, issued several materially false or misleading statements:

a) Galena's press release, dated November 3, 2014, reported "Abstral (fentanyl) sublingual tablet net revenue was $1.6 million in Q3 2014 and $6.1 million to date this year, ***with reiterated guidance of $8-$10 million for the full year 2014***…. Galena's press release also quoted Defendant Schwartz as stating: "'***The company continues to make excellent progress on our clinical programs, and we continue to build our commercial franchise***.'" (Press Release issued November 3, 2014; *see also* Form 10-Q filed November 5, 2014, signed by Schwartz).

b) [Lento:] "As noted in our press release, and as Ryan will review in greater detail, our Abstral net revenue was $1.6 million in Q3. As discussed last quarter, this increase in revenue was expected, and was a result of ***fluctuations in inventory at the wholesale and distribution level***. This is not uncommon, as we're still in the first year of our product launch.

Our daily paid prescriptions or pulled through sales from our customers have continued to improve through the end of Q3, with an even stronger demand in the first month of Q4. Over time, we expect the ex-manufacturer sales to more closely reflect our daily paid prescription volume. As a reminder, Abstral is a supportive care therapy in a segmented and highly competitive market.

According to Wolters Kluwer, our market share of the branded TIRF market in September remained steady with 6% of total prescriptions. The size of the overall TIRF market has fluctuated since our launch, and we remain focused on targeting ***the long-term and sustainable business within the market.*** We strongly believe in the potential of Abstral because of its unique clinical attributes, which are advantageous for patients.

***

Earlier this year, we modified our program rules after carefully gathering feedback from our customers. These rule changes have vastly improved Galena and Abstral's financial position while continuing to ease the financial burden and the out-of-pocket costs for Abstral patients. ***These changes have allowed our prescribers to more appropriately and effectively utilize the voucher and co-pay elements of our patient assistance program.***

As a result our current program helps to cover 96% of all out-of-pocket costs for commercially insured patients. And we have decreased our spending in this program by over 60% since Q1. As we shared on prior calls, the implementation of Galena patient services, known as GPS, has assisted our customers in gaining prior authorization approval and insurance coverage for their patients in a very efficient manner. ***With GPS, our voucher and co-pay programs, we now have the needed resources in place to support patients and providers, and to support the future growth of our commercial brand.***

***

For Abstral, we remain on track to achieve our guidance projections in 2014. ***While we're on [sic] only one month into the quarter, many of our internal performance metrics, including whole-seller and distributor sales reports, as well as REMS and IMS data, report towards -- point towards our strongest quarterly performance to date***." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

c) [Schwartz:] "Thank you, Ryan. As we look back on our first year of commercial activities, we're proud of the structure we have built. While Chris highlighted some the challenges, we also know how to address and adapt to them, as the market has changed for Abstral, ***our commercial team has refined our strategy to ensure the long-term viability and profitability of the franchise***.

We'll be taking the same expertise into our launch of Abstral. ***As a result, we plan to increase our Abstral revenues by over 50% next year and are setting our 2015 net revenue guidance to between $15 million and $18 million***." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

d) [Analyst] "… Could you talk a bit more about what you're seeing, what are the signs that the distributors and wholesalers are starting to hone in on the right level of inventory for Abstral to better match the demand, quarter over quarter? And what sort of inventory build are you expecting in 4Q?

> [Lento:] "I'll take the first part of that question. ***Some of the internal metrics we are monitoring, as you know, we're keeping track of daily sales, average prescription price, number of prescribers, and we're off to a terrific start in Q4. Along with our wholesale and distributor partners, we're learning how to manage Abstral during this year.*** It is a product six strengths being managed – being managed at eight different wholesalers, with dozens of distribution centers. ***So we are feeling more confident in our ability, and in our partners' ability to manage the inventory moving forward***." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

e) "In March of 2014 we launched the Galena Patient Services (GPS) program, a full service support program designed to navigate patient access to Abstral that is coordinated through a third party vendor. Along with the launch of GPS, we also made changes to our patient assistance program (PAP) to reduce the use of free product vouchers and rely more heavily upon an expedited prior authorization process. These changes resulted in both a flattening in the growth in prescription demand and significant improvement in gross-to-net deductions, quarter-over-quarter in 2014. ***We believe the slowed growth in quarter-over-quarter prescription demand is the temporary result of our GPS program and PAP rules changes, and we anticipate an increase in prescription demand and ex-manufacturer sales in the last quarter of 2014***." (Form 10-Q filed November 5, 2014, signed by Schwartz).

[Emphasis added.]

79. Defendants' November 3, 2014 and November 5, 2014 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading by touting Abstral's November sales and expected revenues (bullet a-e) while exclusively attributing increasing revenues to legitimate and sustainable practices such as the alignment of wholesale and distribution inventory levels and the cessation of the "temporary" downturn following rule changes to Galena's patient assistance programs. In reality, as Defendants' knew, Abstral's improving revenues were the result of Galena's illegal kickbacks to Drs. Ruan and Couch who were overprescribing Abstral for non-medically necessary purposes to gain personal profit.

80. In particular, Defendants' statements that Galena experienced "stronger demand in the first month of Q4" (bullet b), that Galena's "internal performance metrics" for the first "month into the quarter" "point towards our strongest quarterly performance to date" (bullet b), and that "we're off to a terrific start in Q4" (bullet d) while solely attributing the Q4 sales increases to

equalizing "fluctuations in inventory at the wholesale and distribution level" (bullet b) and "our ability, and our partners' ability, to manage inventory moving forward" (bullet d) were materially false or misleading. In truth, the increase in Abstral sales "in the first month of Q4" (bullet b) was *largely based on the rebate agreement* that Defendant Schwartz had entered into with C&R Pharmacy on October 1, 2014, which provided significant kickbacks to Drs. Couch and Ruan for the Abstral prescriptions they wrote. *See* Exhibit 5 (showing extreme increase in the doctors' Abstral prescriptions in October 2014). Similarly, Defendants' statements that "we plan to increase our Abstral revenues by over 50% next year and are setting our 2015 net revenue guidance to between $15 million and $18 million" (bullet c), that Galena "reiterate[s] [its] guidance of $8-$10 million for the full year 2014" (bullet a), and "we anticipate an increase in prescription demand and ex-manufacturer sales in the last quarter of 2014" (bullet e) while attributing the expected increased sales in Q4 and 2015 to innocent causes such as the commercial team's "refined" strategy (bullet c) and the dissipation of the temporary slowdown "following Galena's GPS program and PAP rules changes" (bullet e) were materially false or misleading. Here again, the expected Abstral sales increases were, in reality, largely based on Galena's illegal kickback arrangement between with C&R Pharmacy.

81. Accordingly, Defendants' statements were materially misleading because they failed to disclose that the touted financial results and guidances were achievable as a result of, and were reliant on, Galena's illegal rebate agreement with two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in order to earn the illegal kickbacks. These omissions were material since the undisclosed facts created a significant risk that Abstral revenues were unsustainable.[16]

[16] Indeed, Galena's Forms 10-K evidence Defendants' knowledge that their conduct was illegal, with Galena stating: "The federal Anti-Kickback Statute prohibits persons from knowingly and willfully

2. March 5, 2015 Statements

82. On March 5, 2015, the Company announced its fourth quarter and year end 2014 financial results and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $3.2 million in the fourth quarter of 2014 and $9.3 million for the year ended December 31, 2014, compared to $1.3 million and $2.5 million, respectively, for the same periods of 2013***…. Dr. Schwartz continued,…[,] ['a]dditionally, ***we anticipate the commercial arm of our business to continue to grow revenue, while enhancing our relationships in the oncology community*** as our development pipeline advances. ***As reported today, we recorded our strongest Abstral quarter to date, hitting above the middle of our guidance range for the year***, and with the addition of our second commercial product in Zuplenz, we expect to nearly double our overall commercial sales in 2015.'… Dr. Schwartz concluded, 'Our commercial and clinical teams have done a tremendous job over the past year to advance our multiple programs. ***As I assess our company, I am not only excited about the next 6-12 months, but for the long-term prospects of Galena Biopharma***.'"(Galena's March 5, 2015 press release; *see also* Form 10-K filed March 5, 2015, signed by Schwartz).

b) [Schwartz:] "Our focus is on building Galena into a leading oncology Company. We established our commercial franchise as a strategic component for ***long-term growth, and sets a foundation for our future***. . . . As Chris will elaborate, the relationships that our commercial team is making now with key ***oncology*** healthcare providers, distributors, and managed care groups are not only extremely valuable for selling our current products, but also provide the ability to quickly add future products**.** Finally, ***we expect the commercial business to maximize revenues, become accretive, and provide money to the Company*** to help fund our development assets and minimize shareholder dilution." (Earnings conference call with Defendants Schwartz and Lento participating).

c) [Lento:] "Thank you, Gavin. Today I will walk you through the 2014 successes we have had with our flagship product Abstral….

As noted in our press release, and as Ryan will review in greater detail, ***our actual net revenue was $9.3 million in 2014. We achieved this number with a focused***

---

soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. The Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry…. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only Medicare and Medicaid programs."

> ***sales effort, and we are excited for continued growth of Abstral in 2015.*** As a reminder, Abstral is indicated for the treatment of breakthrough cancer pain, and it is a TIRF, or a transmucosal immediate release fentanyl, product. As Mark mentioned, Galena is an oncology Company, and we are ***steadfastly focused on building Galena's commercial business within the oncology space***.
>
> …With that background, I would like to walk you through the metrics are use to evaluate our business. We acquired the US marketing rights for Abstral from Orexo and relaunched the product in the fourth quarter of 2013. ***We relaunched Abstral that had previously sold approximately $1 million over its previous 12-month period, and we were able to grow the brand to $9.3 million in net revenue in 2014. We believe that we can continue to grow Abstral***, and our successful commercialization will carry over to the relaunch of Zuplenz in Q2.
>
> ***
>
> ***In addition, on slide number 21 you can see the dramatic impact of our patient assistance rule changes and our GPS services have had on increasing the average number of Abstral units dispensed per pay transaction.*** In December 2013, the average units of Abstral per ***pay*** transaction was roughly 42 tablets. ***Fast forward to December 2014, and the average number increased roughly 60% to 69 tablets per transaction. In addition to GPS and the program rule changes, providers have become more comfortable prescribing Abstral for their breakthrough cancer pain patients***." (Earnings conference call with Defendants Schwartz and Lento participating).

[Emphasis added.]

83. Defendants' March 5, 2015 statements (in Galena's press release, Form 10-K, and earnings call) were materially false or misleading. Specifically, Defendants' statements touting the Company's revenues and prospects for future revenues (bullets a-c) and the "strongest Abstral quarter to date" (bullet a) while attributing those record revenues to the legitimate practices such as the successful GPS program and increased Abstral prescriptions to "breakthrough cancer pain patients" (bullet c), were materially false or misleading because the increased revenues were actually the result of illegal and unsustainable practices. In particular, the record Abstral revenues (bullet a) and the significant increase in paid transactions in December 2014 compared to December 2013 (bullet c) were largely the result of the illegal rebate agreement that Defendant Schwartz signed with C&R Pharmacy, which provided kickbacks to Drs. Couch and Ruan for the non-voucher Abstral prescriptions they wrote. Indeed, by the time of these statements, Galena had paid more than $97,000

in "rebates" to Drs. Ruan and Couch for their Abstral prescriptions. *See also* Section IV.C.2.b, *supra* (showing that more than $1.257 million of Galena's first quarter revenue came from Drs. Ruan and Couch's prescriptions).

84. Thus, Defendants' statements were materially misleading because they failed to disclose that the touted financial results were achieved through, and were reliant on, Galena's illegal rebate agreement with two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks payments from Galena. These omissions were material since these undisclosed facts created a significant risk that Abstral revenues were unsustainable.

3. May 7, 2015 Statements

85. On May 7, 2015, the Company announced its financial results for the first quarter ended March 31, 2015 and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $2.8 million in the first quarter of 2015, a 28% increase compared to $2.2 million for the same period a year ago***…. Dr. Schwartz concluded, '***[O]n the commercial front, Abstral sales remain on target, our oncology presence continues to grow, and we reiterate our full year guidance of $15-$18 million for 2015***. Additionally, we are now preparing to launch Zuplenz in July, adding a second, supportive care commercial product to our oncology-focused sales portfolio. In total, we have established a strong foundation with our development programs supported by our commercial franchise, and we remain committed to the growth of our company.'" (Galena's May 7, 2015 press release; *see also* Form 10-Q filed May 7, 2015, signed by Schwartz).

b) [Schwartz:] "***In addition to the development team's accomplishments, our commercial team recorded its second-best quarter of net revenue in the best back-to-back month since Abstral's product launch. Most importantly, we continued our increased penetration within the oncology space*** as we head into the launch of our second commercial oncology supportive care product, Zuplenz." (Earnings conference call, with Defendants Schwartz and Lento participating).

c) [Lento:] "Thank you, Gavin, and good afternoon, everyone. ***As we shared with today's earnings release and as shown on slide number 11, we reported actual net revenue of $2.8 million for the first quarter of 2015, our second-highest quarter of net revenues since our relaunch of Abstral in 2013. In addition, the overall trend line as measured by end-user product demand continues to grow with March representing one of our best months to date.*** Equally important, our

> gross to net deduction also improved this quarter, from 63% in Q4 2014 to 65% in Q1 2015. ***One month into the second quarter, our performance metrics indicate a very strong month for Abstral in April as measured by customer demand***, but please remember that this is not a direct correlation to our net revenue, which is recorded based on ex-factory sales.
>
> ***We continue to focus on refining Abstral's prescription fulfillment process as depicted on slide number 12.*** As a reminder, Abstral is an indicator for the treatment of breakthrough cancer pain in opioid tolerant adult cancer patients.
>
> ***
>
> Our current market share in the branded turf market remains steady at around 5% of total prescriptions on a monthly basis measured by Wolters Kluwer. ***While our salesforce continues to call on pain specialists who are treating a large number of cancer patients, our long-term strategy is to develop lasting relationships with medical oncologists, radiation oncologists, and palliative care specialists since we believe this represents the most stable market, the best potential for Abstral, and meets the goals as an oncology-focused organization***." (Earnings conference call, with Defendants Schwartz and Lento participating).

[Emphasis added.]

86. Defendants' May 7, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading. Defendants' statements touting Abstral's revenues (bullets a, c, and d) while attributing that revenue to legitimate prescriptions, resulting from "[m]ost importantly, …our increased penetration within the oncology space" (bullet b; *see also* bullet c), increased "end-user product demand" (bullet c), and Galena's "refin[ed] Abstral's prescription fulfillment process" (bullet c) were materially false or misleading because the increased revenues were, in reality, the result of illegal and unsustainable practices that encouraged the over-prescriptions of Abstral for non-medically necessary purposes. In truth, the record Abstral revenues were largely the result of the rebate agreement that Defendant Schwartz signed with C&R Pharmacy, which provided significant kickbacks to Drs. Couch and Ruan for the Abstral prescriptions. Indeed, while Defendants touted that "March represent[ed] one of our best months to date" due to "end-user product demand continu[ing] to grow" (bullet c), it is evident from the chart of Drs. Ruan and Couch's prescriptions that Abstral sales in March were largely fueled by the increased prescriptions

written by Drs. Ruan and Couch following the execution of the rebate agreement. *See* Exhibit 5, attached hereto.

87. Thus, Defendants' statements were materially misleading because they failed to disclose that the touted financial results and Galena's net sales and revenues were achieved through Galena's illegal kickbacks paid to two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral for non-medically necessary purposes in an attempt to earn payments from Galena. These omissions were material since these undisclosed facts created a significant risk that Abstral revenues were unsustainable due to Galena's illegal conduct that facilitated the revenues.

4. August 6, 2015 Statements

88. On August 6, 2015, Galena announced its financial results for the second quarter ended June 30, 2015 and, in doing so, issued a series of materially false or misleading statements:

a) Galena's press release, dated August 6, 2015, reported "***[n]et revenue was $3.4 million in the second quarter of 2015, a 48% increase compared to $2.3 million reported for the same period in 2014. Net revenue was $6.1 million in the first half of 2015, a 36% increase compared to $4.5 million reported for the same period in 2014***." Galena's press release also quoted Defendant Schwartz as stating: "'***And, today we reported improved Abstral sales quarter over quarter resulting in our strongest net revenue quarter to date. Based on current projections, we anticipate that we will come in closer to the lower end of our guidance range, at around $15 million for the year***.'" (Press Release issued August 6, 2015; *see also* Form 10-Q filed August 6, 2015, signed by Schwartz).

b) [Schwartz:] "***As we noted in our press release, we recorded net revenue of $6.1 million thus far this year from Abstral sales, and are very proud of our Commercial team for bringing in our highest quarterly net revenue to date of $3.4 million in Q2.***

Abstral is part of the transmucosal immediate release fentanyl, or TIRF, market that is very competitive, and has received a great deal of press this year. ***As Chris will go into in more detail, our metrics for Abstral are trending in the right direction, although our sales growth has fluctuated quarter-over-quarter based on field demand and wholesaler inventory levels.***

Because of the ongoing market dynamics, the quarterly variability around our reported sales, and the fact that we've just launched Zuplenz and have yet to

recognize revenue to date for that product, it is appropriate for us to guide to a lower end of our range with the expected full-year revenue of around $15 million for both products. We continue to work to make our Commercial business accretive, and we are evaluating our commercial options and strategy to achieve long-term profitability and maximize the value of our commercial assets, with a goal of building shareholder value." (Earnings conference call on August 6, 2015 with Defendants Schwartz and Lento).

c) [Lento:] "Thank you, Gavin. And good afternoon, everyone. I'll start my discussion with Abstral. As a reminder, Abstral is indicated for the treatment of breakthrough cancer pain in opioid-tolerant adult cancer patients, and falls under the TIRF REMS Access program. ***I am pleased to report Abstral net revenue of $3.4 million for the second quarter of 2015 -- our highest net revenue quarter since launch.***

This is a result of our team adding new prescribers and the continued adoption of our Galena patient services, or GPS program. On slide 16, you can see this trajectory. In addition, our gross to net deduction improved to 77% this quarter compared to 65% in Q1 2015.

***

As we have mentioned on previous calls, the growth of Abstral will continue to fluctuate quarter-over-quarter. But as you have seen, the underlying metrics are all trending upwards.

***

Our account management team has secured product availability with all of our distribution partners, assuring product access for all healthcare providers and their appropriate patients.

***

In summary, ***our Abstral business is growing***, and we are enthusiastic about selling Zuplenz where our very early reception of the product has been positive." (Earnings conference call on August 6, 2015 with Defendants Schwartz and Lento participating).

[Emphasis added.]

89. Defendants' August 6, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading because they falsely asserted that Abstral's "underlying metrics are all trending upwards" (bullet c) or in the "right direction" (bullet b) and that "our Abstral business is growing" (bullet c), when the exact opposite was true. In actuality, the two

doctors responsible for ***30%*** of the Company's Abstral prescriptions had been arrested and their ***businesses shut down in May 2015***, which resulted in "significantly" reduced Abstral sales (as David Corin, Galena's National Sales Director, testified). Moreover, while Defendants attributed the disappointing earnings to "ongoing market dynamics" (bullet b), this was materially misleading given that the actual reason for the lower earnings was that Galena had lost its two top Abstral prescribers because the doctors had been arrested for writing illegal prescriptions outside the usual course of professional practice and not for a legitimate medical purpose—illegal prescriptions that had been induced by Defendants' kickbacks. Thus, Defendants' statements misled investors by failing to disclose that Abstral's revenues were not sustainable, certainly not at the reported level. Defendants' statements were also materially misleading because they still attributed Abstral sales to legal and sustainable practices while attributing the disappointing earnings entirely to normal circumstances; in truth, Abstral sales in the first part of the quarter had been significantly propped up by Drs. Ruan and Couch who had overprescribed Abstral in order to receive illegal kickback payments from Galena.

90. On the news of Galena's disappointing earnings and reduced revenue guidance, the Company's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close at $1.51 on August 7, 2015. The August 6, 2015 disclosures of underperforming earnings and lower expectations partially revealed the risks concealed by Defendants' misstatements. In particular, these disclosures revealed the materialized risk that Abstral sales would drop off when the illegal kickbacks from Galena and illegal prescriptions for Abstral written by Galena's top two prescribers could not be sustained. Indeed, this is exactly what happened when (although not disclosed by Galena) law enforcement closed down Drs. Ruan and Couch's practices, clinics, and pharmacy in late May 2015. This disclosure, however, was only partially corrective. Galena's stock price would have dropped more if the full truth—that the revenue losses would only grow based on the government shutdown

of Galena's highest Abstral prescribers—had been revealed. Thus, the August 6, 2015 disclosures were both actionably misleading and partially corrective.

B. The Truth Emerges With Galena's November 9, 2015 Corrective Disclosure

91. On November 9, 2015, Galena announced in a press release that it had decided to divest its commercial business, which included Abstral. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. In making this announcement, Galena made the following materially false or misleading statements, quoting Schwartz:

> "Dr. Schwartz continued, '***When I assumed the position of President and CEO of Galena, I, along with our executive team, began a careful examination of our operations and assets to determine the optimal strategy for Galena that would enable the greatest opportunity for growth, while maximizing shareholder value. As a result of this analysis and review by our Board of Directors, we have concluded that it is in the best interest of our patients, our shareholders, and the long-term success of our company to focus our energy and resources exclusively on our clinical development programs.*** Since acquiring the products we have significantly grown the sales of Abstral and successfully launched Zuplenz, and I believe that each has strong commercial potential and offers significant benefits to their respective patient populations. ***However, the foundation of Galena has always been our cancer immunotherapy programs, which are now rapidly advancing towards several key inflection points. Therefore, we believe it is important for Galena to focus on our core expertise and the successful advancement of our late and mid stage clinical pipeline.*** We appreciate the dedication and hard work of the commercial team as we transition out of the commercial business and are extremely grateful for all of their efforts.'
>
> Dr. Schwartz concluded, 'For both patients and shareholders of Galena, there is a much greater opportunity to generate value if we dedicate all of our resources to our clinical programs, and we are eager to move the company in this new direction….'"
>
> [Emphasis added.]

92. On the November 9, 2015 news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015.

93. The November 9, 2015 disclosures of the discontinuation of Galena's commercial business sufficiently revealed the risks concealed by Defendants' misstatements. That is, these

disclosures revealed the risk concealed by Defendants that the commercial operations of Galena could not be sustained without the illegal promotion by Galena and illegal prescriptions for Abstral written by Galena's top two prescribers. These disclosures revealed the true severity of those risks in that the sales drop off (more than 30% of the Abstral business lost when Drs. Ruan and Couch were forced to shut down) was so pronounced that Galena's entire commercial business had to be discontinued.[17]

94. On November 20, 2015, the Company announced that it had sold its Abstral product to a private company in a deal valued at up to $12 million, with $8 million cash up-front, and up to $4 million in additional cash upon the achievement of certain sales milestones, effective as of November 19, 2015.

C. Loss Causation

95. Defendants' materially false and misleading created an undisclosed risk that Abstral sales would drop off when the illegal kickbacks from Galena and illegal prescriptions for Abstral written by Galena's top two prescribers could not be sustained. Here, that is precisely what happened.

96. Indeed, the undisclosed risk began to materialize when law enforcement shut down Drs. Ruan and Couch's practices, clinics, and pharmacy in late May 2015. As David Corin (Galena's National Sales Director) confirmed in his testimony, Abstral sales "***dropped significantly***" after Drs. Ruan and Couch were shut down. Accordingly, following the closure of Drs. Ruan and Couch's practices, Galena was forced to announce disappointing earnings and reduced revenue guidance on August 6, 2015. In response, the Company's stock price fell 7.4%. The August 6, 2015 disclosure, however, was only partially corrective. Galena's stock price would have dropped more if the full

[17] Plaintiffs allege, in the alternative, that a class period could run from August 6, 2015 through November 9, 2015, based on Defendants' materially false or misleading statements on August 6, 2015, following the known closure of Drs. Ruan and Couch's practices.

truth—that the Abstral product line was not viable without the illegally-induced prescriptions from Drs. Ruan and Couch (Galena's two highest Abstral prescribers)—had been revealed.

97. This truth finally revealed itself to the public on November 9, 2015 when the Company announced the divestment of Galena's commercial business. This disclosure revealed the full materialization of the concealed risk—that Galena's Abstral product could not be sustained without artificial sales from Drs. Ruan and Couch's who wrote 30% of all Abstral prescriptions in order to receive illegal kickback payments from Galena. David Corin specifically attributed Galena's divestment of its commercial business to the loss of Drs. Ruan and Couch's illegal prescriptions, with Mr. Corin testifying that Galena "***couldn't make up that revenue***" that had been lost by Drs. Ruan and Couch "[a]nd eventually Galena was forced to sell [Abstral] in December 2015."[18]

D. Motive

98. Throughout the Class Period, Defendants used Galena's artificially inflated stock to finance its operations. The Company was dependent upon financing to supplement the modest revenues generated from its only salable product, Abstral. As Galena disclosed in its SEC filings, "[i]n the absence of revenue from the commercialization of Abstral, Zuplenz or our product candidates, our potential sources of operational funding are proceeds from the sale of equity and

[18] While Defendants' materially false and misleading statements also concealed the risk that the Company was exposed to litigation and potential liability, the slow rate at which the legal risks were partially revealed to the public significantly complicates loss causation for the undisclosed risk of liability. Indeed, information leaked out through reporting on Drs. Ruan and Couch's criminal trial. Further, by the time the DOJ issued its September 8, 2017 press release announcing its settlement with Galena, the Company had already announced its agreement to complete a reverse merger, wherein Galena was to be acquired by Sellas Life Sciences. The agreement on the reverse merger was finalized on August 8, 2017. As reported by a biopharmaceutical analyst: "The reverse merger with Sellas could breathe new life into Galena, which has had a disappointing year. In March, the company announced it was looking for a company to acquire its holdings, two months after its CEO Mark W. Schwartz quit amid a federal investigation into the company's marketing strategy for its opioid Abstral (fentanyl)." *See* https://www.pharmalive.com/bay-area-galena-biopharma-merges-with-oncology-focused-biopharma-in-all-stock-deal/.

funded research and development payments and payments received under partnership and collaborative agreements."

99. Further, the Company's operating losses had significantly increased during the Class Period. According to Galena's March 5, 2015 earnings press release, operating losses for the year ended December 31, 2014 were $52.2 million compared to an operating loss of $33.8 million for the year ended December 31, 2013. As explained in the press release: "The increase in net operating loss year-over-year is primarily the result of our increased activity and enrollment in our Phase 3 PRESENT trial for NeuVax, our investigator sponsored trials for NeuVax, and our Phase 2 trial for GALE-401, as well as increased selling and marketing expenses associated with the growth of our commercial activities." Because of these increased losses, the Company needed outside financing to maintain its operations and to finance the ongoing clinical trials of its primary drug candidate NeuVax.

100. Thus, on November 18, 2014, the Company entered into a purchase agreement with Lincoln Park Capital, LLC ("LPC") that gave the Company the right to sell to LPC up to $55 million in shares of the Company's common stock over the 36 month term of the purchase agreement ("Purchase Agreement"). The Purchase Agreement provided that "[t]he purchase price of shares of Common Stock pursuant to the Purchase Agreement will be based on the prevailing market price at the time of sale, but in no event will shares be sold to LPC on a day the Common Stock closing price is less than the 'floor price' as set forth in the Purchase Agreement." The agreement defined the "floor price" as "$1.00, which shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such reorganization, recapitalization, non-cash dividend, stock split or other similar transaction, the Floor Price shall mean the lower of (i) the adjusted price and (ii) $1.00."

101. LPC initially purchased 2.5 million shares of Galena common stock, pursuant to the Purchase Agreement. As a result of this initial issuance, the Company received initial net proceeds of $5 million. In addition to the LPC's initial purchase of common stock, during 2014, Galena received net proceeds of $8.5 million from LPC's subsequent purchases of a total of 4.6 million shares.

102. During each of the years ended December 31, 2014 and December 31, 2015, respectively, the Company received $2.3 million in net proceeds from the sale of 1.4 million shares of common stock through At Market Issuance Sales Agreements.

103. In addition, through a public offering that closed on March 18, 2015, the Company sold units consisting of common stock and warrants at $1.56 per unit for proceeds of $40.8 million.

104. Each of these financings were possible through, and facilitated by, the artificially inflated stock price. Had Abstral revenues not been inflated through Defendants' undisclosed illegal kickbacks to prescribers, including two doctors who were overprescribing Abstral for non-medically necessary purposes, the above financings would not have been available. Thus, Defendants were motivated to commit the fraud alleged herein in order to keep the Company's operations ongoing while its product candidates were in clinical development.

105. That Defendants had a specific incentive to issue materially false or misleading information bolsters an inference of scienter based on the other allegations of Defendants' specific knowledge.

106. After the corrective disclosures, including the announced divestment of Galena's commercial division, Galena was unable to secure financing at terms that were nearly as favorable as those it was able to obtain when Defendants were artificially inflating the Company's stock price through materially false and misleading statements. Indeed, when the Company announced a public offering on January 7, 2016, it disclosed that units consisting of common stock and warrants would

be sold at a price of $1.10 per unit—a 30% decrease from the Company's public offering that closed on March 18, 2015.

107. In addition, after Galena was forced to announce the divestment of its commercial line, Galena's stock price immediately dropped, as discussed *supra*. Galena's stock price continued to drop in the months that followed, and on August 8, 2016, Galena had to amend its Purchase Agreement with LPC to account for the fact that the Company's stock was trading under the $1.00 "floor price" by "remov[ing] the 'floor price' at which the purchase price of shares of our common stock may be sold to LPC on a given day." The amended Purchase Agreement was notably less advantageous to Galena and established new protections for LPC, including that LPC could not be obligated to make a single regular purchase exceeding $2,000,000 and that "Company may deliver an Accelerated Purchase Notice to the Investor only on a Purchase Date on which the Closing Sale Price is not below $0.50."

E. Summary of Allegations Demonstrating Defendants' Violations of Sections 10(b) and 20(a) of The Exchange Act and SEC Rule 10b-5

108. A summary of the allegations supporting Plaintiffs' 10(b) and 20(a) claims, include the following:

- Defendants tracked, and closely monitored prescriptions of Abstral by doctor through "an internal document that [Galena] would send out on a quarterly basis with all of our prescribers in the country, how many prescriptions they had written each quarter." This document showed that a phenomenal ***30%*** of all Abstral prescriptions were written by ***just two*** doctors—Drs. Ruan and Couch. *See* ¶¶71-77.

- Schwartz and Lento frequently communicated with Drs. Ruan and Couch, via email and in person, and provided, among other things, "more than 85 free meals to doctors and staff from a single, high-prescribing practice" (PPSA) which DOJ described as kickbacks to the physicians (Ruan and Couch). Schwartz made at least two trips to Mobile to visit Drs. Ruan and Couch: one trip in November 2014 and one trip in February 2015. Lento and Mr. Corin also made several trips to Mobile to visit Drs. Ruan and Couch at the direction of Defendant Schwartz, including trips on September 24, 2014, January 20, 2015, and April 21, 2015. According to Corin, "***[Schwartz] wanted us to have a more regular cadence in our visits" to***

Drs. Ruan and Couch. Defendants also repeatedly urged Drs. Ruan and Couch to participate in Galena's "RELIEF" program, which paid doctors $500 for every Abstral patient they enrolled. According to the DOJ, Galena's RELIEF program was "nominally designed to collect data on patient experiences with Abstral, but which acted as a ***means to induce the doctors to prescribe Abstral***." As to PPSA, Galena not only paid Dr. Couch for his enrollment of non-cancer patients in the RELIEF program, but also made special arrangements for Dr. Couch, allowing him to enroll three times more patients than other doctors and paying him up to five times more per patient ($2,500 per patient instead of $500 per patient). Defendants' trips and promotions were designed to encourage Drs. Ruan and Couch to continue prescribing inexplicably large amounts of Abstral. As Corin testified, Drs. Ruan and Couch were "important" to Galena "[b]ecause they were our highest Abstral prescribers" by "a large margin." *See* ¶¶64-70; *see also* 42-48.

- Following a noticeable decrease in the number of prescriptions written by Drs. Ruan and Couch (as a result of a rule change to Galena's voucher program), Defendants entered into the rebate agreement with Drs. Ruan and Couch' pharmacy, C&R Pharmacy, which provided illegal kickbacks to Drs. Ruan and Couch to increase the doctors' prescriptions of Abstral. Indeed, Corin testified that he made a trip to Mobile, AL on September 24, 2014 to visit with Drs. Ruan and Couch to try to come to "find a way to partner up" with the doctors, and their pharmacy, "***in order to add additional profit to C&R's prescrib[ing] or dispensing of Abstral***." The result was the rebate agreement, which was signed by Defendant Schwartz. Galena, in fact, paid these illegal kickbacks as evidenced by FBI Special Agent Amy White' testimony that Galena ***wire transferred $97,924*** to C&R Pharmacy on February 18, 2015. *See* ¶¶49-63.

- The number of prescriptions for Abstral from Dr. Ruan and Dr. Couch increased after the rebate agreement was executed, according to testimony from Mr. Corin. This significant increase is also reflected in an internal Galena document, provided by a confidential witness, which shows that Drs. Ruan and Couch's Abstral prescriptions for the fourth quarter of 2014 provided nearly ***$1.26 million*** in revenue to Galena—***more than half*** of any ***total*** revenue Galena had reported ***for any quarter*** by that time. ¶61; *see* Ex. 5 (chart entered into evidence at the doctors' trial, showing uptick in prescriptions). Indeed, after entering into the rebate agreement, Galena reported materially increased revenues. ¶62.

- Defendants Schwartz and Lento paid the illegal kickbacks to Drs. Ruan and Couch despite knowing since at least October 2013 that these doctors treated few, if any, cancer patients but that these doctor's prescriptions of Abstral were nevertheless significantly higher than other doctors by huge and inordinate margins (making up 30% of all Abstral prescriptions). Accordingly, Defendants were on specific notice that their Abstral sales—

propped up by illegal kickbacks—were at serious risk of being unsustainable. Indeed, as Defendants knew, federal and state governments strictly enforce the rules governing kickbacks and prescriptions written for non-medically necessary purposes. *See* Section IV.B.2, *supra*.

- In light of the above, and Defendants' knowledge of and involvement in the conduct, Defendants' statements (on November 3 and 5, 2015, March 5, 2015, May 7, 2015, and August 6, 2015) that attributed Abstral sales to legal and sustainable practices, were materially false or misleading.

- Drs. Ruan and Couch's practices, clinics, and pharmacy were raided and shut down by law enforcement on May 20, 2015, as a result of an extensive joint investigation by the FBI and DEA. As David Corin (Galena's National Director of Sales) testified, Galena ***knew*** that Dr. Ruan and Dr. Couch's "practice was shut down," and Galena's "volume [of Abstral prescriptions] dropped … ***significantly***" after that shut down in "late May 2015." ¶76.

- In light of the foregoing, Defendants' August 6, 2015 statements that the Company's Abstral sales were "trending in the right direction" and "growing" were materially false or misleading. As Mr. Corin testified, Galena "***couldn't make up that revenue***" that had been lost from Drs. Ruan and Couch "[a]nd eventually Galena was forced to sell the product [Abstral] in December 2015." ¶76. Indeed, just three months after Defendants' statements touting Abstral sales, Galena was forced to announce that it was divesting its commercial business and thus ***discontinuing Abstral sales***.

109. The above allegations, when considered in their totality, strongly support Plaintiffs' claims that Defendants knowingly or recklessly issued materially false or misleading statements to the investing public, and that these statements artificially inflated the price of Galena stock thereby causing financial losses for investors who purchased the Company's stock during the Class Period. *See also, supra,* Section V.A (detailing Defendants' materially false or misleading statements); Section V.C (discussing Plaintiffs' loss causation allegations); Section V.D (discussing Plaintiffs' motive allegations to further support scienter).

VI. CLASS ACTION ALLEGATIONS

110. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that acquired Galena's securities from November 3, 2014 through November 9, 2015, inclusive, or in the

alternative from August 6, 2015 through November 9, 2015, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

111. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Galena's common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Galena shares were traded publicly during the Class Period on the NASDAQ. As of February 28, 2015, Galena had 133,702,578 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Galena or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

112. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

113. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

114. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Galena; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

115. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VII. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

116. The market for Galena's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Galena's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Galena's securities and market information relating to Galena, and have been damaged thereby.

117. During the Class Period, the artificial inflation of Galena's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, resulting in the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Galena's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Galena and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant

times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period caused Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

118. At all relevant times, the market for Galena's securities was an efficient market for the following reasons, among others:

(a) Galena stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Galena filed periodic public reports with the SEC and/or the NASDAQ;

(c) Galena regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Galena was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

119. As a result of the foregoing, the market for Galena's securities promptly digested current information regarding Galena from all publicly available sources and reflected such information in Galena's stock price. Under these circumstances, all purchasers of Galena's securities during the Class Period suffered similar injury through their purchase of Galena's securities at artificially inflated prices and a presumption of reliance applies.

VIII. NO SAFE HARBOR

120. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Galena who knew that the statement was false when made.

IX. FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

121. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Particularly, Plaintiffs incorporate the allegations in Section V, *supra*.

122. During the Class Period, Defendants made materially false or misleading statements in the Company's quarterly and annual reports filed with the SEC on Forms 10-Q and 10-K, in other documents filed with the SEC, and in the Company's press releases and/or in the Company's conference calls. Defendants misrepresented material facts or failed to disclose material facts required in order to make the statements they made not materially misleading.

123. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Galena's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Galena and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

124. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

125. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants'

material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Galena's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

126. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Galena's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Galena's securities during the Class Period at artificially high prices and were damaged thereby.

127. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Galena was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Galena securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

128. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

129. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

X. SECOND CLAIM

Violation of Section 20(a) of The Exchange Act
Against Defendant Schwartz

130. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Particularly, Plaintiffs incorporate the allegations in Section V, *supra*.

131. Defendant Schwartz acted as a controlling person of Galena within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions and ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendant Schwartz had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendant Schwartz was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

132. In particular, Defendant Schwartz had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

133. As set forth above, Galena and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendants Schwartz is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendant Schwartz's wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: February 18, 2021

Respectfully submitted,

/s/ William B. Federman

William B. Federman (admitted *pro hac vice*)
FEDERMAN & SHERWOOD
10205 N. Pennsylvania Avenue
Oklahoma City, OK 73120
Telephone: (405) 234-1560
wbf@federmanlaw.com

Lead Counsel for the Class

/s/ Gary S. Graifman
Gary S. Graifman, Esq.
KANTROWITZ, GOLDHAMER & GRAIFMAN, P.C.
210 Summit Avenue
Montvale, New Jersey 07645
Telephone: (201) 391-7000

Liaison Counsel for the Class

CERTIFICATE OF SERVICE

This is to certify that on February 18, 2021, I electronically transmitted this document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the counsel of record.

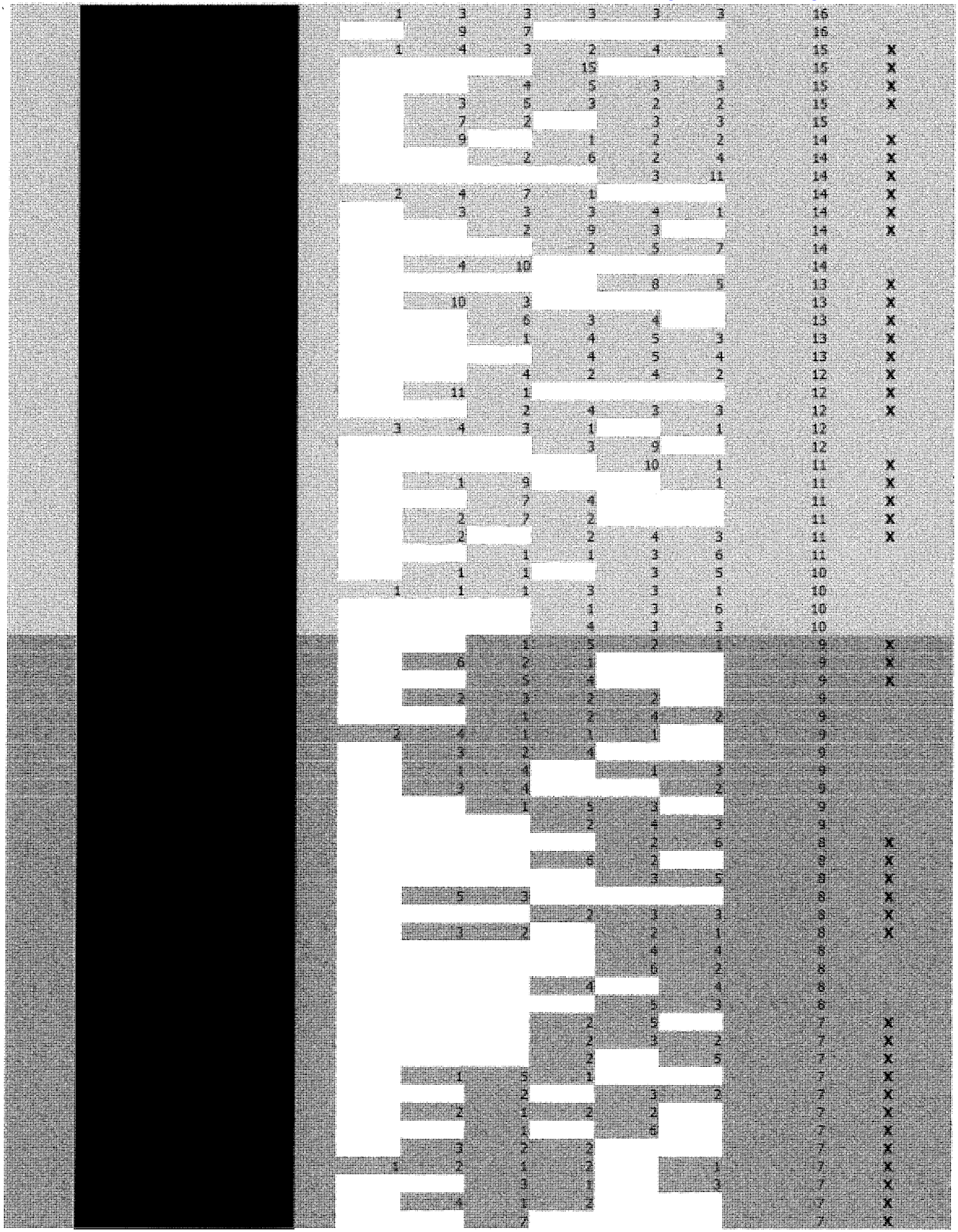
/s/ William B. Federman
William B. Federman

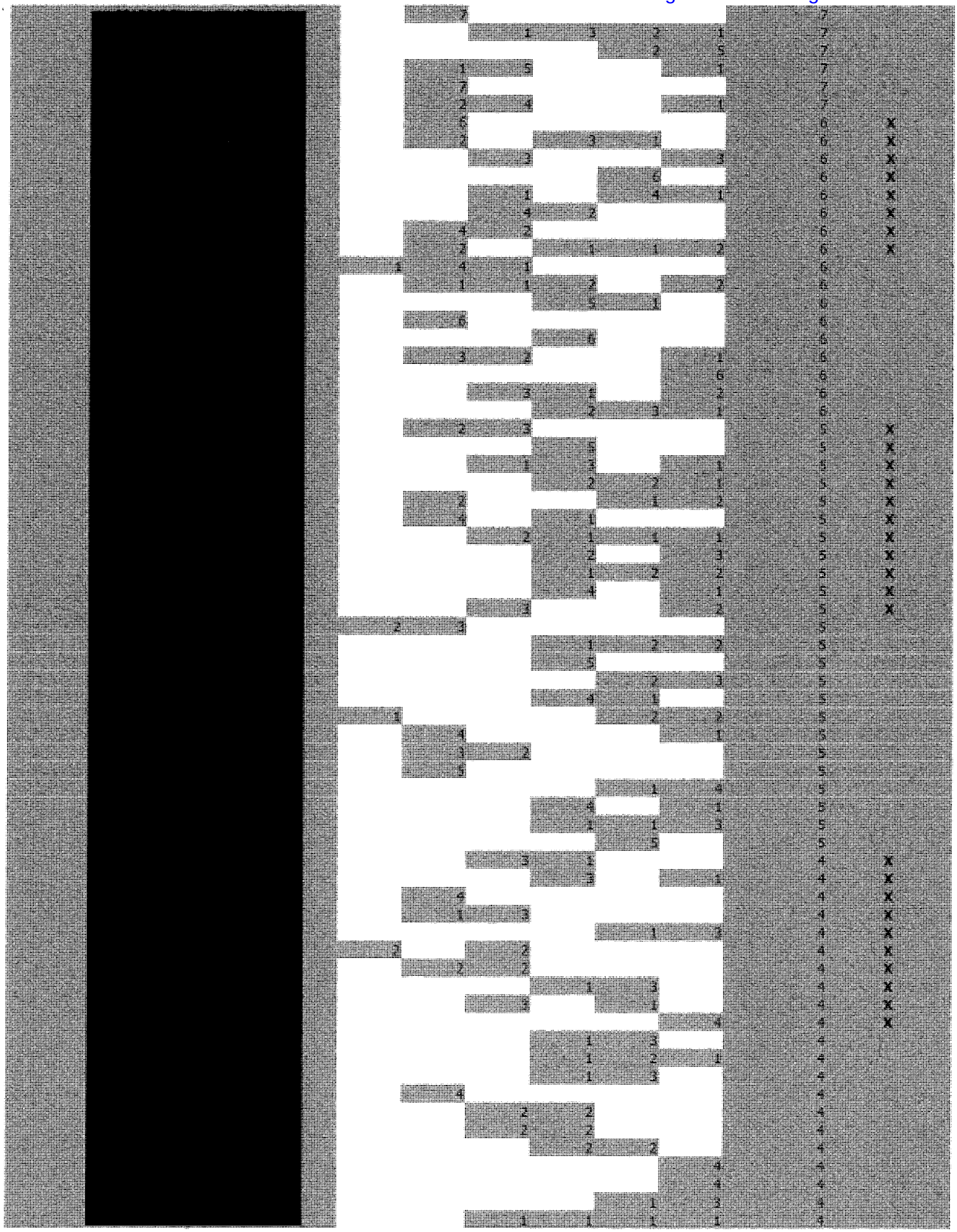
EXHIBIT 1

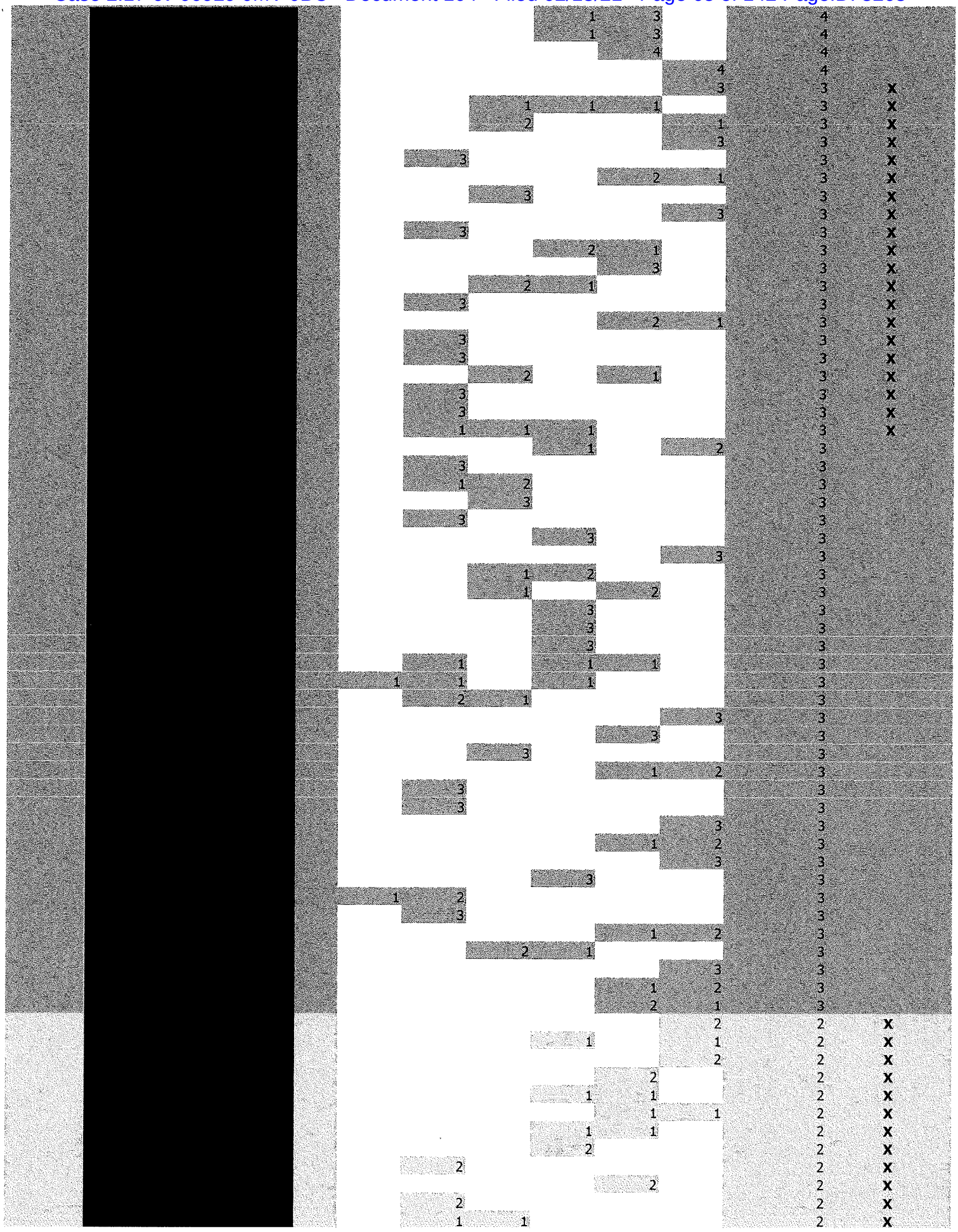
Prescriber REMS ID	Prescriber Last Name	Q3 13	Q4 13	Q1 14	Q2 14	Q3 14	Q4 14	Grand Total	Insys Payment
5926827[redacted]	[redacted]	1	202	467	262	163	205	1308	
5926759[redacted]	[redacted]		71	228	187	93	90	669	
5937809[redacted]	[redacted]	11	98	172	133	105	91	611	X
				19	71	35	28	153	
			42	35	23	23	27	242	X
			35	88	16			239	X
			41	30	12	13	6	211	X
					28	40	36	208	
		9	20			10	63	210	X
			16	21	17	23	12	89	X
			19	17	8	15	13	83	X
			27	23	13	5	5	73	X
			1	12	18	25	15	72	X
		1	3	11	16	19	18	68	X
		1	1	20	17	14	14	67	X
					16	22	34	66	X
			9	12	12	12	9	54	X
					8	17	23	48	X
			22	26				48	
			11	26	6	4		47	X
			28	10	5		3	46	X
			8	9	4	12	9	42	X
			8	17	8	5	3	41	X
			11	21	8			40	X
			7	21	4	3	5	40	X
			11	10	3	8	8	40	X
		2	13	6	5	5	8	39	
			13	13	8	2		36	
				3	7	19	6	35	X
				7	11	8	9	35	X
			4	5	3	13	6	31	X
		1	9	3		7	10	30	X
				3	8	8	11	30	X
			14	3	8	3	1	29	
		1	5	5	6	8	4	29	
			12	15				27	X
				1	9	8	9	27	X
			4	9	4	6	4	27	X
			6		3	11	6	26	X
			7	3	5	4	7	26	
				8	5	8	4	25	X
						2	23	25	
		1	1	9	10	3		24	X
		2	6	6	3	5	2	24	
		1	3	4	3	3	8	22	X
						9	13	22	X
				2	14	4	1	21	X
			6	8	3	1	3	21	
			6	9	4	2		21	
					3	18		21	
				1	1	17	1	20	
		1	4	6	6	1	1	19	X
				1	8	5	5	19	X
				6	3	6	4	19	
					4	8	6	18	X
					1	5	12	18	X
				2		9	7	18	X
				4	5	1	8	18	
					2	5	11	18	
					4	5	8	17	X
			1	11	5			17	X
					10	6	1	17	
		1	3	3	3	3	4	17	
					1	6	9	16	X
					11	4	1	16	X
				3	5	4	4	16	

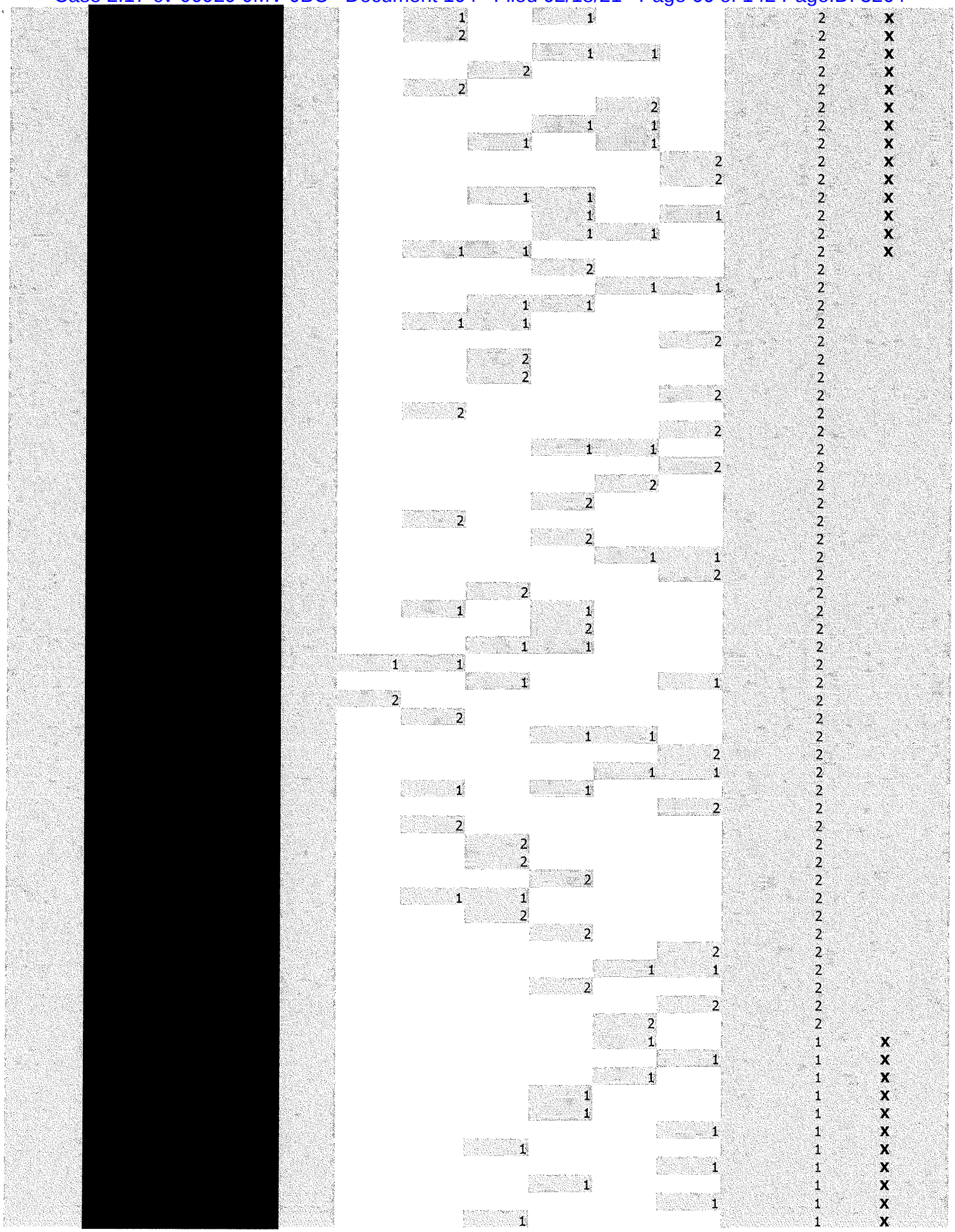
GOVERNMENT EXHIBIT 387 CR-15-[redacted]

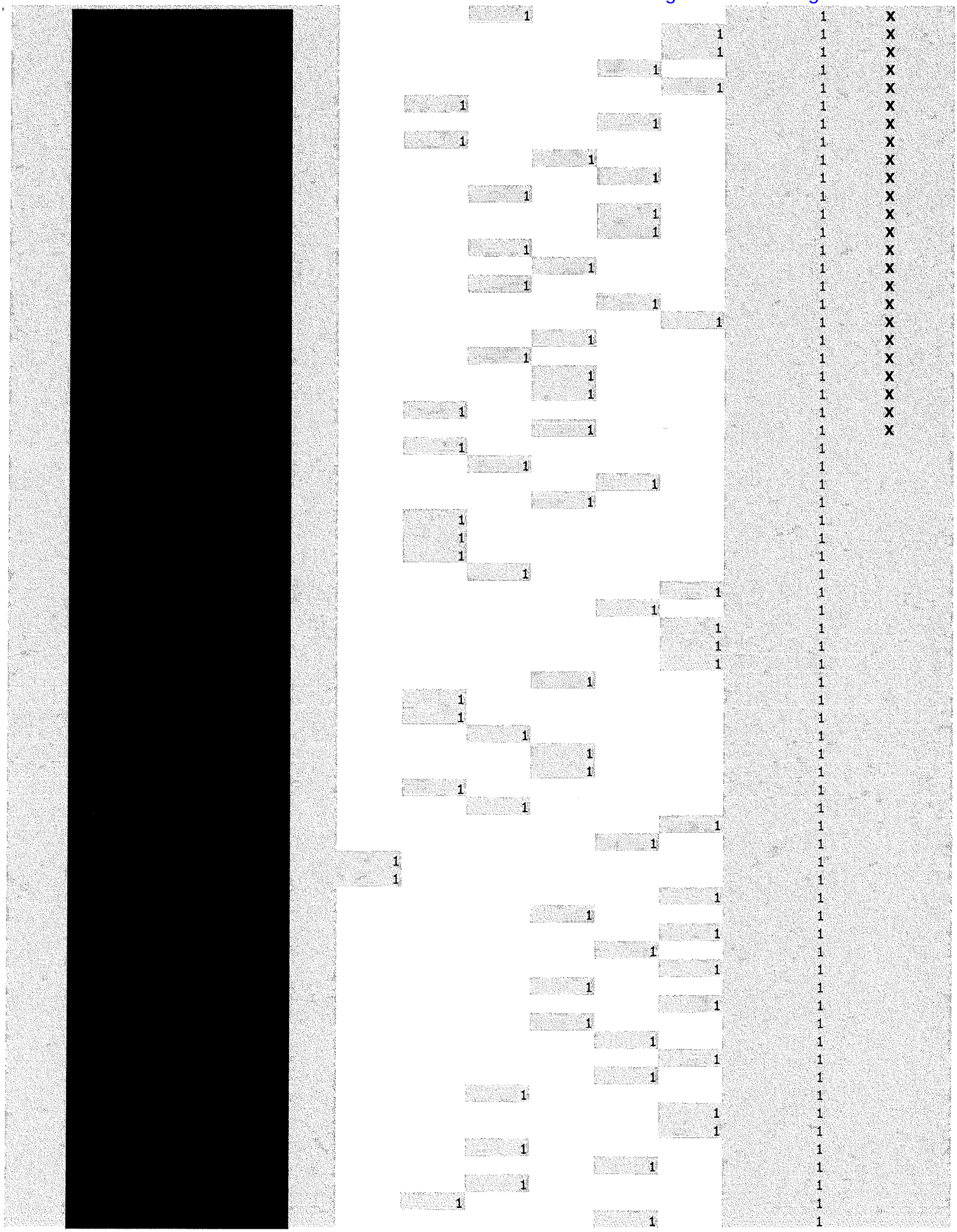
ADMITTED IN EVIDENCE 1/19/17











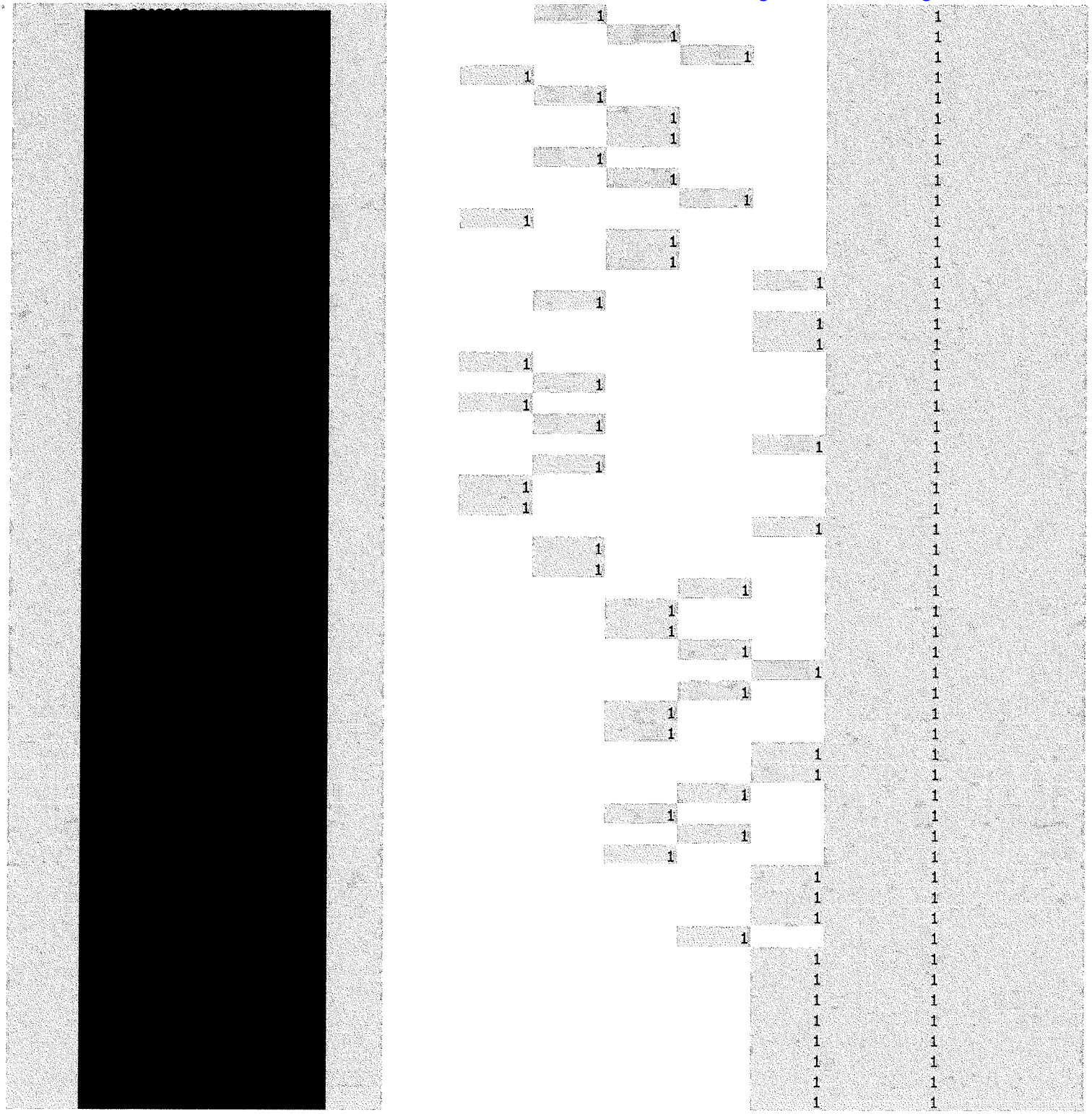


EXHIBIT 2

GALENA
BIOPHARMA

RELIEF Registry FACT SHEET

- **RELIEF** – **R**apid **E**valuation of **L**ifestyle, **I**ndependence, and **E**limination of Breakthrough Cancer Pain with **F**reedom from Oral Discomfort Through the Use of Abstral® (fentanyl) Sublingual Tablets

- Observational patient registry study as indicated for the management of breakthrough pain (BTcP) in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

- Any patient prescribed Abstral® for BTcP is eligible to participate.

- Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program prescriber and patient enrollment required.

- Questionnaire-based study: 4 short web-based patient questionnaires completed over a 1 month study period.

- Patient self-reported outcomes:
  - Quality of Life
  - Pain Measures
  - Ease-of-use
  - Patient Satisfaction

- All patient data is de-identified to maintain HIPAA (Health Insurance Portability and Accountability Act)-compliant confidentiality.

- HCP, nurse, and patient are compensated for their time and effort.

- Multiple HCPs permitted to enroll patients at the same site.

- Individual HCPs may enroll up to 25 patients each.

Please refer interested sites to: Carey Aron, DVM, Director, Clinical Affairs
caron@galenabiopharma.com

EXHIBIT 3

To: Jeff Palmer[jpalmer@galenabiopharma.com]
From: David Corin
Sent: Tue 10/22/2013 10:41:09 PM
Importance: Normal
Subject: Fwd: Abstral RELIEF Registry Program
Received: Tue 10/22/2013 10:41:10 PM

Sent from my iPhone

Begin forwarded message:

From: Chris Lento <clento@galenabiopharma.com>
Date: October 22, 2013 at 6:24:37 PM EDT
To: [redacted]
Cc: Mark Schwartz <mwschwartz@galenabiopharma.com>, David Corin <dcorin@galenabiopharma.com>, Allan Valmonte <avalmonte@galenabiopharma.com>, David Corin <dcorin@galenabiopharma.com>
Subject: FW: Abstral RELIEF Registry Program

Dr. Ruan:

I hope all is well. I was surprised to receive this note today (via Neil). I had thought you were very excited to participate in Galena's RELIEF Registry. I believe there might exist some confusion on patient eligibility. Would it be possible to discuss at your earliest convenience?

I am copying Mark Schwartz, (Galena COO), Allan Valmonte (Director, Clinical Affairs) and Dave Corin (Region Business Director).

Thank you for your consideration.

Chris Lento
Vice President US Sales & Commercial Operations
Office: 207-797-3851
Mobile: 201-396.6984
Fax: 503-400-6149
E-mail: clento@galenabiopharma.com
Skype: Chris.Lento

Galena Biopharma, Inc. (NASDAQ: GALE)
4640 SW Macadam Ave., Suite 270
Portland, OR 97239
LinkedIn Company Profile

Allan,

I want to offer you my humble apology. Dr. Ruan is unable to participate in the registry trial. Evidently, he

was under the impression that the candidates for this study would be patients with non-malignant pain. As we discussed the protocol, he informed me that his practice does not have very many patients who would qualify. I'm really sorry for this misunderstanding.

Best wishes to you. If you would like for me to approach some other physicians in my network, I am available to pursue this opportunity further.

Have a good evening.

Neil Stimpson, CCRC
Sunbelt Research Group, LLC
(251) 689-7477 cell
(251) 382-1823 office
(251) 470-6867 fax

On Oct 22, 2013, at 3:02 PM, Allan Valmonte <avalmonte@galenabiopharma.com> wrote:

Neil,

See attached as I updated our corp address. Other than that, we should be fine. Go ahead and route for signature on your end.

Allan A. Valmonte

Direct: +1.503.400.6624
Mobile: +1.415.609.2524
Fax: +1.503.400.6611
Skype: allan.a.valmonte

<21090332-AB4B-46EB-BA01-BA3B45EE8D60[29].png>
Galena Biopharma, Inc. (NASDAQ: GALE)
4640 SW Macadam Ave., Suite 270
Portland, OR 97239

From: Neil Stimpson [redacted]>
Date: Tuesday, 22 October, 2013 11:16 AM
To: Allan Valmonte <avalmonte@galenabiopharma.com>
Subject: RE: Abstral RELIEF Registry Program

Please see attached draft agreement for Dr. Ruan. Thanks

Neil D. Stimpson, CCRC
Research Director / President
Sunbelt Research Group, LLC
3828 St. Andrews Loop East
Mobile, AL 36693
(877) 391-0609, ext. 1 OFFICE
(251) 689-7477 CELL
(251) 470-6867 FAX

Research Director / President
Sunbelt Research Group, LLC
3828 St. Andrews Loop East
Mobile, AL 36693
(877) 391-0609, ext. 1 OFFICE
(251) 689-7477 CELL
(251) 470-6867 FAX

From: Allan Valmonte [mailto:avalmonte@galenabiopharma.com]
Sent: Friday, October 18, 2013 11:16 AM
To: Neil Stimpson
Subject: Re: Abstral RELIEF Registry Program

Neil,

Attached is the contract template, protocol and ICF. Please take a look at the contract and make any edits to the document in tracked changes. In parallel, take a look at the ICF and protocol to ensure that you are familiar with the procedures of the trial.

If you can remind me again of the IRB you can use? Do you have the forms for them or do you need them from me?

Let me know if you have any questions and if there is anything I can do to assist.

Thanks,

Allan A. Valmonte

Direct: +1.503.400.6624
Mobile: +1.415.609.2524
Fax: +1.503.400.6611
Skype: allan.a.valmonte
<image001.png>
Galena Biopharma, Inc. (NASDAQ: GALE)
4640 SW Macadam Ave., Suite 270
Portland, OR 97239

From: Neil Stimpson [redacted]>
Date: Wednesday, 16 October, 2013 9:02 AM
To: Allan Valmonte <avalmonte@galenabiopharma.com>
Cc: Jeff Palmer <jpalmer@galenabiopharma.com>
Subject: RE: Abstral RELIEF Registry Program

See attached signed CDA.

Neil D. Stimpson, CCRC
Research Director / President
Sunbelt Research Group, LLC
3828 St. Andrews Loop East
Mobile, AL 36693

From: Allan Valmonte [mailto:avalmonte@galenabiopharma.com]
Sent: Tuesday, October 15, 2013 3:40 PM
To: [redacted]t.[redacted]
Cc: Jeff Palmer
Subject: Abstral RELIEF Registry Program

Dear Neil,

Thanks for taking the time to chat today. As I indicated, Jeff Palmer is our TBM and in his conversation with Dr. Ruan, there is interest in the Abstral RELIEF Registry Program. Therefore, I'm attaching our CDA. If you find the language acceptable, please go ahead and sign off on the PDF version. The Word version is equivalent in that if you require edits, please do so in tracked changes and then send back to me for review.

Once we have the CDA in place, I can send over the contract template, protocol and ICF template in preparation for IRB approval.

Let me know if you have any questions and I look forward to working with you on the Registry program.

Best,

Allan A. Valmonte

Direct: +1.503.400.6624
Mobile: +1.415.609.2524
Fax: +1.503.400.6611
Skype: allan.a.valmonte
<image001.png>
Galena Biopharma, Inc. (NASDAQ: GALE)
4640 SW Macadam Ave., Suite 270
Portland, OR 97239

<image001.png>

<image002.png>

<RuanReliefAgreement-draft aav.docx>

EXHIBIT 4

REBATE AGREEMENT

This Rebate Agreement ("Agreement") is made as of October 1, 2014 ("Effective Date") by and between Galena Biopharma, Inc. ("Galena") and C & R Pharmacy LLC ("C & R").

A. Galena is a pharmaceutical manufacturer, which develops and markets specialty drugs used in the treatment of cancer.

B. C & R is a licensed pharmacy.

C. The parties agree to the following terms and conditions in furtherance of an arrangement under which Galena 's products ("the Products") will be made available to C & R at a discounted price.

1. THE PRODUCTS.

The Products subject to this Agreement are identified on Exhibit "A", attached hereto, and incorporated herein by this reference.

2. THE SOURCE.

The Products may be purchased by C & R through any drug wholesale distributor licensed by the corresponding State Board of Pharmacy.

3. THE REBATE.

C & R will provide proof of purchases of the Products to Galena by the 5th day of each month, which proof of purchase will identify the Products purchased during the immediately preceding month, as well as their quantity and price. Galena will pay to C & R, by the 30th day after the end of each calendar quarter, a rebate based on the following structure:

NOTE: Below rebate rates are based on non-voucher prescription dollars:

Low Range	High Range	Rate Adjustment
$ -	$ 225,000	8.75%
$ 225,000	$ 275,000	9.0%
$ 275,000	$ 325,000	9.5%
$ 325,000	$ 375,000	10.0%
$ 375,000	$ 425,000	10.5%
$ 425,000	$ 525,000	11.0%
$ 525,000	$ 675,000	15.0%
$ 675,000	$ 925,000	18.0%
$ 925,000	$ 10,000,000	20.0%

51266693.1

ADMITTED IN EVIDENCE 11/9/17

GOVERNMENT EXHIBIT 38-8 02-15-18-CG

LOYALTY PROGRAM REBATE. In addition to the structure above, Galena agrees to pay C & R an additional 5% rebate on all purchases at the end of four calendars if the monthly average for that period exceeds $400,000.00 in non-voucher prescription dollars. The loyalty program rebate is paid annually.

4. THE TERM.

Term.

The term of this Agreement shall commence on the Effective Date, and shall terminate one year from the Effective Date, unless earlier terminated in accordance with this Agreement; provided, however, that the Agreement will be automatically renewed unless either Party gives written notice to the other within sixty (60) days of the beginning of the new calendar year.

Termination Without Cause.

Either Party may terminate this Agreement in whole, without cause. In the event C & R shall determine to terminate the Agreement, C & R shall provide Galena written notice of such termination, effective upon Galena's receipt of the notice. In the event Galena shall determine to terminate the Agreement, Galena shall provide C & R with at least sixty (60) days prior written notice of such termination.

Termination For Cause.

Either Party may terminate this Agreement upon thirty (30) days written notice thereof to the other upon the occurrence of the following event: the other Party materially breaches this Agreement and does not cure such breach within thirty (30) days of receipt of such notice.

The Agreement may be terminated immediately by either Party if one Party becomes bankrupt or insolvent or makes an unauthorized assignment or goes into liquidation or proceedings are initiated for the purpose of having a receiving order or winding up order made against it or the other Party applies to the courts for protection from its creditors.

The Agreement may be terminated immediately by either Party if C & R has submitted a utilization report to Galena which Galena determines, in its sole judgment, contains claims which are not due and payable under this Agreement; or a Party is found guilty of or liable for fraud or making false claims.

The Agreement may be terminated immediately by either Party if there is a material change in any applicable federal, state, or local law or regulation that affects either the value of this Agreement or either Party's compliance obligations under this Agreement.

5. RECORDS.

C & R will retain all records evidencing purchase of the Products for a period of not less than one year, and will make such records available to Galena upon request.

6. DELIVERY SERVICES.

All products sold by C & R Pharmacy are picked up from their pharmacy in Mobile, AL.

7. CONFIDENTIALITY.

This Agreement is confidential between the parties hereto, and neither party, nor its employees, shall disclose, its existing or the terms thereof to any third party.

8. DISPUTES.

In the event a dispute shall arise regarding the interpretation or enforcement of this Agreement or any of its terms, resulting in legal action being taken, each party will be responsible for its own attorneys' fees and costs incurred thereby.

9. GOVERNING LAW.

This Agreement shall be interpreted in accordance with, and governed by, the laws of the State of Oregon, without regard to its conflicts of law principles.

10. NOTICE.

Notice to Galena shall be sent to:

Galena Biopharma, Inc.
Nate Ide, Director, National Accounts
4640 SW Macadam Avenue, Suite 270
Portland, OR 97239

Notice to C & R shall be sent to:

C & R Pharmacy LLC
Caye McConaghy Renegar, Supervising Pharmacist
4682 Airport Blvd, Suite A
Mobile, AL 36608

11. **COMPLIANCE WITH LAWS.**

Each Party represents that its performance under this Agreement will be in full compliance with any and all applicable laws, regulations and guidance. C & R shall comply with all applicable laws relating to the dispensing of the Products purchased under this Agreement. C & R shall at all times be responsible for providing drugs to its customers, in C & R's independent judgment, are in the best clinical interest of those patients.

12. DISCOUNTS & PRICE REPORTING

The Parties agree that all discounts, rebates, or other reductions in price pursuant to this Agreement are "discounts and other reductions in price" under Section 1128B(b)(3)(A) of the Social Security Act (42 U.S.C. § 1320a-7b(b)(3)(A)). Galena and C & R agree to comply with the discount statutory exception, 42 U.S.C. § 1320a-7b(b)(3)(A), and the applicable Discount Safe Harbor regulations, 42 C.F.R. § 1001.952(h), which relate to Galena's obligation to report and disclose any discounts, rebates, and other reductions to C & R for the Products purchased under the Agreement. C & R shall report all discounts to reimbursing agencies (including without limitation Medicare and Medicaid) and other entities, maintain records thereof, and provide information to reimbursing agencies and other governmental agencies upon request, in accordance with all applicable laws and regulations, including without limitation 42 C.F.R. § 1001.952(h) and 42 U.S.C. § 1320 a-7b(b)(3)(A).

Where a price concession is required to be reported to the Centers for Medicare and Medicaid Services or any state-operated health care program under the Discount Safe Harbor to the Federal Anti-kickback Statute, C & R shall fully and accurately report such price concession. To the extent that the price concession may be determined at the time of sale, Galena hereby informs C & R that the value of the price concessions attributable to the sale are as reflected in this Agreement. To the extent that the value of the price concession is not known at the time of sale, C & R acknowledges that the sales made under this Agreement reflects a price concession that is not known at the time of sale. When the value of the discount becomes known, Galena shall provide C & R with documentation of the calculation of the price concession identifying the specific goods or services purchased to which the price concession will be applied.

13. COUNTERPARTS.

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall constitute a single instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the day first above written.

GALENA BIOPHARMA, INC.

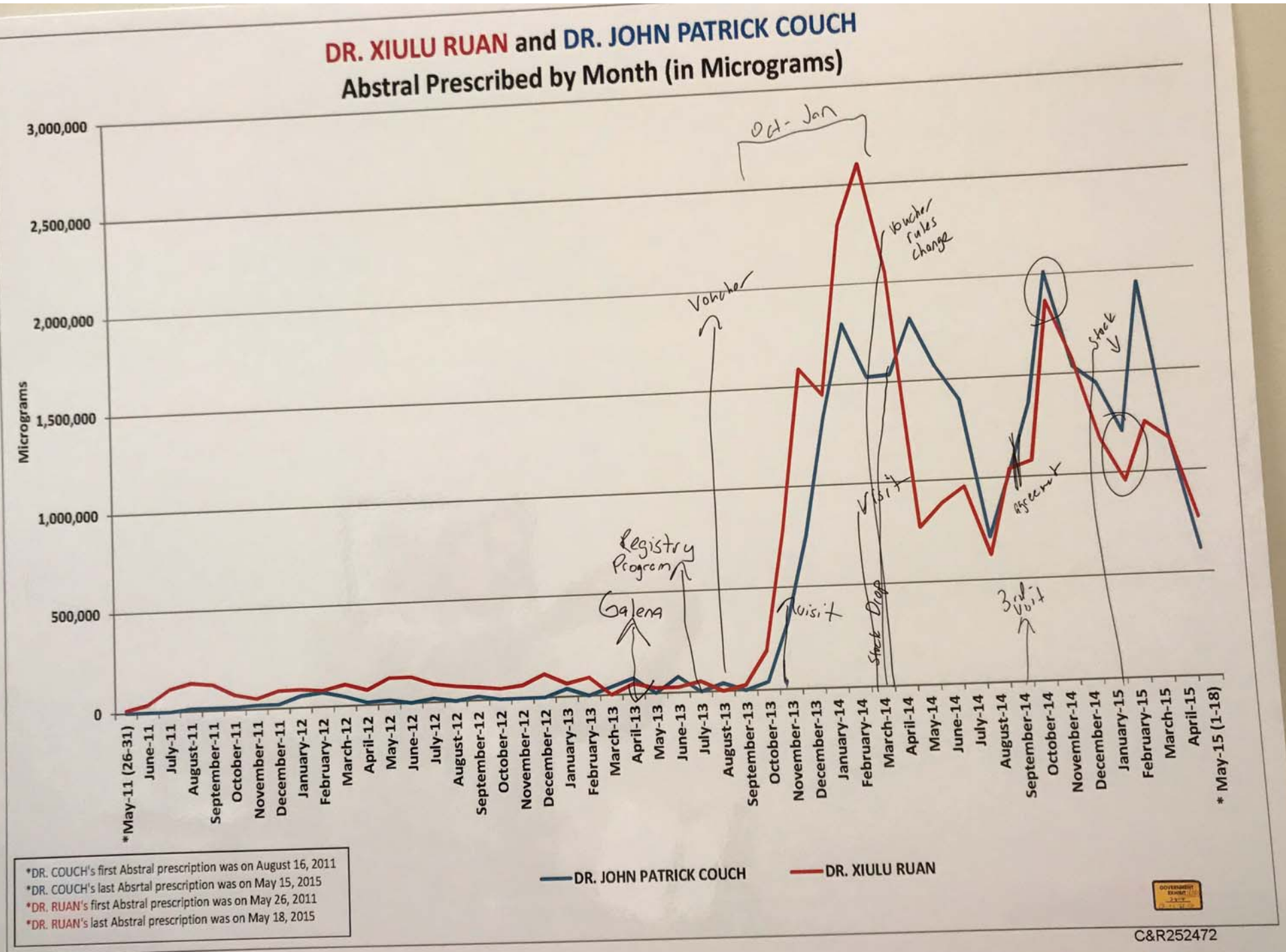
C & R Pharmacy LLC

51266693.1

EXHIBIT "A"

ITEM AND NDC #
57881-331-32 Abstral (fentanyl) 100 mcg, 32 sublingual tablets
57881-332-32 Abstral (fentanyl) 200 mcg, 32 sublingual tablets
57881-333-32 Abstral (fentanyl) 300 mcg, 32 sublingual tablets
57881-334-32 Abstral (fentanyl) 400 mcg, 32 sublingual tablets
57881-336-32 Abstral (fentanyl) 600 mcg, 32 sublingual tablets
57881-338-32 Abstral (fentanyl) 800 mcg, 32 sublingual tablets

EXHIBIT 5



C&R252472

EXHIBIT 6

DAG/CJB

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	*	**CRIM. NO. 15-00088-CG**
	*	**USAO NO. 13R00521**
v.	*	
	*	**VIOLATIONS: 18 USC § 1962(d)**
JOHN PATRICK COUCH, M.D. and	*	**21 USC § 846**
XIULU RUAN, M.D.	*	**21 USC § 841(a)(1)**
	*	**18 USC § 1349**
	*	**18 USC § 371**
	*	**18 USC § 1956(h)**
	*	**18 USC § 1957**
	*	**Forfeiture Notices**

SECOND SUPERSEDING INDICTMENT

THE GRAND JURY CHARGES:

I. INTRODUCTION

At all times relevant to this Second Superseding Indictment:

THE DEFENDANTS

1. Defendant **JOHN PATRICK COUCH, M.D.** was a Mobile, Alabama physician with a medical degree from the Medical College of Georgia. He was licensed to practice medicine in the State of Alabama, and obtained a Drug Enforcement Administration (hereinafter "DEA") Registration Number which allowed him to dispense Controlled Substances.

2. Defendant **XIULU RUAN, M.D.** was a Mobile, Alabama physician with a medical degree from Shandong Medical University, located in Jinan, China. He was licensed to practice medicine in the State of Alabama, and obtained a DEA Registration Number which allowed him to dispense Controlled Substances.

PAIN CLINIC AND PHARMACY

3. Together, **COUCH** and **RUAN** owned and co-directed a pain management clinic

named Physician's Pain Specialists of Alabama, P.C. (hereinafter "PPSA"). PPSA had two clinic locations in Mobile, Alabama — one located at 2001 Springhill Avenue, and the other located at 4682 Airport Boulevard. **COUCH** was listed as the registered agent for PPSA.

4. **COUCH** and **RUAN** also co-owned a pharmacy named C&R Pharmacy, which was located adjacent to the PPSA clinic on Airport Boulevard in Mobile, Alabama. **COUCH** was the registered agent for C&R Pharmacy.

APPLICABLE FEDERAL LAW

5. The Controlled Substances Act (hereinafter "CSA") governs the distribution and dispensing of various listed drugs, including narcotics, that are prescribed by physicians and other licensed health care providers. Licensed physicians and physician extenders may distribute and dispense Controlled Substances if they have a DEA Registration number and if they comply with all DEA regulations and all applicable federal laws.

6. The CSA assigns legal authority for the regulation of Controlled Substances to the DEA. The statute charges DEA with the prevention, detection, and investigation of the diversion of Controlled Substances from legitimate channels while at the same time ensuring that adequate supplies are available to meet legitimate domestic medical, scientific and industrial needs.

7. The DEA issues registration numbers to qualifying persons, who are authorized to dispense Controlled Substances. To issue a prescription for a Controlled Substance, a physician must be licensed to practice by a state authority and must have a DEA registration number.

8. Under Title 21, United States Code, Section 802(21) the term practitioner is defined as a "physician . . . registered, or otherwise permitted by the United States or the jurisdiction in which the he practices . . . to distribute, dispense, . . . administer, . . . a Controlled Substance in the course of professional practice . . . " Under Title 21, United States Code,

Section 822(a)(2), every person or entity who handles Controlled Substances must be registered with DEA or be exempt by regulation from registration. The DEA registration grants practitioners federal authority to handle Controlled Substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located.

9. The practitioner is responsible for the proper prescribing and dispensing of Controlled Substances prescribed under his or her name. The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state. Controlled Substances may only be distributed or dispensed lawfully in the manner prescribed by the mechanism created by the CSA.

10. Provisions of the CSA mandate that the person or entity registered with DEA must be able to account for all Controlled Substances which have been received, distributed, dispensed, or disposed.

11. Title 21, Code of Federal Regulations, Sections 1306.05, 1306.11, and 1306.21 require a prescription for a Controlled Substance to be dated as of, and signed on, the day issued, bearing the patient's full name and address, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and DEA registration number of the prescriber.

CONTROLLED SUBSTANCES

12. Defendants **COUCH** and **RUAN** each obtained DEA Registration Numbers, which allowed them to dispense Controlled Substances. Between January 1, 2011 and May 20, 2015, **COUCH** and **RUAN** wrote approximately 285,000 prescriptions for Controlled Substances.

13. The CSA, Title 21, United States Code, Section 801, *et seq.*, and its implementing regulations set forth which drugs and other substances are defined by law as "Controlled Substances." Those Controlled Substances are then assigned to one of five schedules — Schedule I, II, III, IV, or V — depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.

14. The term "Schedule I" means the drug has no currently-accepted medical use and lacks safety under medical supervision. Schedule I substances cannot legally be prescribed.

15. The term "Schedule II" means the drug or other substance has a high potential for abuse, the drug has a currently accepted medical use with severe restrictions, and abuse of the drug or other substances may lead to severe psychological or physical dependence. Certain Schedule II drugs have a high potential for abuse. This abuse can lead to addiction, overdose, and sometimes death.

16. The term "Schedule III" means the drug or other substance has a high potential for abuse, but less than the drugs listed in Schedule II, the drug has a currently accepted medical use with severe restrictions, and abuse of the drug or other substances may lead to severe psychological or physical dependence.

17. The term "Schedule IV" means the drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III, the drug or other substance has a currently accepted medical use in treatment, and abuse may lead to limited (relative to the drugs or substances in Schedule III) physical or psychological dependence.

18. Title 21, Code of Federal Regulations, Section 1306.04(a) state that a valid prescription for a Controlled Substance must be issued for a legitimate medical purpose by an

individual practitioner acting in the usual course of his professional practice. An Order purporting to be a prescription issued not in the usual course of professional practice, or in legitimate and authorized research, is not a prescription within the meaning and intent of Section 309 of the Act (21 U.S.C. § 829). The person knowingly issuing it shall be subject to the penalties provided for violations of the provisions of law relating to Controlled Substances.

19. Certified Automation of Reports and Consolidated Orders System (hereinafter "ARCOS") is an automated, comprehensive drug reporting system maintained by DEA, which monitors the flow of Controlled Substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. ARCOS accumulates these transactions, which are then summarized into reports. These DEA reports give investigators in Federal and state government agencies information that can then be used to identify the diversion of Controlled Substances into illicit channels of distribution.

20. **COUCH** and **RUAN** regularly prescribed large quantities of the following Controlled Substances at PPSA:

A. **Oxycodone**: The generic name for a highly addictive prescription analgesic. The use of oxycodone in any form can lead to physical and/or psychological dependence, and abuse of the drug may result in addiction. It is classified as a Schedule II Controlled Substance, and is sold generically or under a variety of brand names, including OxyContin, Roxicodone, Percocet, and Endocet.

B. **Oxymorphone:** The generic name for a highly addictive prescription analgesic. The use of oxymorphone in any form can lead to physical and/or psychological dependence, and abuse of this drug may result in addiction. It is classified as a Schedule II Controlled Substance, and is sold generically or under a variety of brand names, including Opana.

C. **Hydrocodone**: The generic name for a highly addictive prescription analgesic. The use of hydrocodone in any form can lead to physical and/or psychological dependence, and abuse of this drug may result in addiction. As of October 6, 2014, hydrocodone is classified as a Schedule II Controlled Substance. Prior to this date, it was classified a Schedule III Controlled Substance It is sold generically or under a variety of brand names, including Lortab, Norco, Zohydro, and Vicodin.

D. **Hydromorphone:** The generic name for a highly addictive prescription analgesic. The use of hydromorphone in any form can lead to physical and/or psychological dependence, and abuse of this drug may result in addition. It is classified as a Schedule II Controlled Substance, and is sold generically or under a variety of brand names, including Exalgo and Dilaudid.

E. **Fentanyl**: The generic name for a highly addictive prescription analgesic. The use of fentanyl in any form can lead to physical and/or psychological dependence, and abuse of this drug may result in addiction. It is classified as a Schedule II Controlled Substance. It is sold generically or under a variety of brand names, including Subsys, Abstral, Lazanda, Fentora, and Duragesic.

F. **Morphine**: The generic name for a highly addictive prescription analgesic. The use of morphine in any form can lead to physical and/or psychological dependence, and abuse of this drug may result in addiction. It is classified as a Schedule II Controlled Substance. It is sold generically or under a variety of brand names, including Avinza, MsContin, and Kadian.

G. **Benzodiazepines:** The generic name for an addictive class of psychoactive drugs that are used to treat a variety of medical issue, including depression, panic disorders, anxiety disorders, and insomnia, among others. The use of benzodiazepines can lead to physical and/or

psychological dependence, and abuse of these drugs may result in addiction. The benzodiazepine class of drugs is classified as Schedule IV Controlled Substances. Common brand names of benzodiazepines include Xanax (generic: alprazolam); Valium (generic: diazepam), and Klonopin (generic: clonazepam), among many others.

H. **Carisoprodol:** The generic name for a centrally acting skeletal muscle relaxant. Carisoprodol is classified as a Schedule IV Controlled Substance. It is sold generically or under the brand name Soma.

21. Beginning in 2013, **RUAN** became not only one of the most prolific purchasers of Controlled Substances in the State of Alabama, but also in the entire United States. He regularly out-purchased doctors in much larger cities in the United States.

22. In the State of Alabama, **RUAN** was the number one purchaser of both oxycodone and morphine in 2011, 2012, 2013, 2014, and 2015. **RUAN** was also the top purchaser of fentanyl in the State of Alabama in 2012, 2013, and 2014.

23. The amount of Controlled Substances purchased by **RUAN** was not only extremely high as compared to other doctors within the State of Alabama, but also as compared to doctors throughout the United States.

24. In 2013 and 2014, **RUAN** ranked amongst the top purchasers of oxycodone, morphine, hydrocodone, and fentanyl in the entire United States.

25. In 2015, **RUAN** only purchased controlled substances for five months before his arrest on May 20, 2015. However, even when compared to other doctors nationwide who purchased drugs over twelve months in 2015, **RUAN** was still nationally ranked in morphine, oxycodone, and fentanyl.

26. Many of the prescriptions issued by defendants **RUAN** and **COUCH** were not

issued for a legitimate medical purpose and were not issued within the usual course of professional medical practice.

PAIN MANAGEMENT

27. The discipline of pain medicine is a recognized medical sub-specialty practiced by physicians in the United States. Legitimate pain medicine experts have specialized knowledge, education, training, and experience and utilize a multi-disciplinary approach.

28. Despite some aspects of legitimate medical practice at PPSA, **RUAN** and **COUCH** ran what was, in essence, a pill mill. Their primary method of pain management was writing multiple prescriptions for high doses of Schedule II, III, and IV Controlled Substances, including, but not limited to: oxycodone (brand names: OxyContin, Roxicodone, Percocet, and Endocet), oxymorphone (brand name: Opana), hydrocodone (brand names: Lortab, Norco, Zohydro, and Vicodin) hydromorphone (brand names: Exalgo and Dilaudid), fentanyl (brand names: Subsys, Abstral, Lazanda, Fentora, and Duragesic), and morphine (brand names: MsContin, Avinza, and Kadian). Some of these prescriptions were diverted and/or abused by drug traffickers and addicts.

TIRF DRUGS

29. Transmucosal instant-release fentanyl ("TIRF") drugs are a subset of other fentanyl-based drugs. TIRF drugs are sold under several brand names, including Subsys, Abstral, Fentora, and Lazanda, all of which are Schedule II Controlled Substances.

30. The primary difference between these brands is how the fentanyl is delivered to the patient: Subsys is an oral spray; Abstral is a dissolvable tablet placed under the tongue; Fentora is a buccal tablet placed in the cheek; and Lazanda is a nasal spray.

31. The only FDA-approved indication for TIRF drugs is "for the management of

breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their persistent pain."

32. Since fentanyl is approximately 100 times more potent than morphine, and 40–60 times more potent than 100% pure heroin, fentanyl in TIRF drugs is measured in micrograms.

33. Due to the extreme risk of misuse, abuse, addiction, and overdose death associated with TIRF drugs, the FDA requires that all practitioners, pharmacists, and patients must be enrolled in an FDA Risk Evaluation & Management Strategy ("REMS") program before they are allowed to prescribe, dispense, or take Subsys, Abstral, Fentora, or Lazanda.

34. Before prescribing a TIRF drug to a patient, the prescriber must fill out and sign a REMS form which explicitly states, "I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain."

35. TIRF drugs are exceptionally expensive. Insurance providers for PPSA patients who were prescribed TIRF drugs were billed anywhere from just under $1,000.00 per month for a patient prescribed 30 doses of Subsys 100mcg, all the way up to over $21,000.00 per month for a patient prescribed 240 doses of Subsys 1,200mcg.

36. Due to both the exceptional danger and expense of TIRF drugs, many insurance providers required prior approval before they reimbursed for a TIRF prescription.

37. Between January 2011 and May 20, 2015, **COUCH** and **RUAN** wrote over 6,000 prescriptions for TIRF drugs to approximately 1,000 different PPSA patients. Virtually all of these patients filled their expensive TIRF drug prescriptions at C&R Pharmacy, which was owned by **COUCH** and **RUAN**.

38. Of the approximately 1,000 different PPSA patients prescribed TIRF drugs by

RUAN and **COUCH**, only a small percentage actually had cancer.

BILLING REQUIREMENTS

39. A National Provider Identifier ("NPI") is a unique billing number assigned to physicians, as well as to physician extenders, who have the capability of billing for patient services. The unique NPI under which a bill is submitted is a critical component used by healthcare insurance providers to determine whether a particular patient service will be reimbursed, and if so, for how much. Physicians are typically reimbursed at a higher rate than physician extenders.

40. Defendants **COUCH** and **RUAN** both had their own unique NPIs. They also employed physician extenders, such as physician's assistants ("PA"), certified registered nurse practitioners ("CRNP"), and certified registered nurse anesthetists ("CRNA") at PPSA. Some of the physician extenders at PPSA also had their own unique NPIs.

41. One of the insurance companies billed by PPSA, Blue Cross/Blue Shield of Alabama ("BC/BS"), required claims to be billed under the name and NPI of the physician or physician extender who actually rendered the service. The BC/BS billing guidelines stated,

> "Under no circumstances should services performed solely by a [physician extender] be billed under a physician's name and NPI. However, a physician may bill for these services under his/her name and NPI if the physician also sees and renders services to the patient, reviews the notes of the physician extender, and concur with the findings."

42. These guidelines are in place, because BC/BS typically reimbursed at a higher rate for services provided by a physician, as opposed to the same services provided by a physician extender.

43. BC/BS, Cigna, United Healthcare, Tri-Care, and Medicare, among other insurance companies who provide healthcare coverage, are all "healthcare benefits programs" as

that term is defined in Title 18, United States Code, Section 24(b).

UNDERCOVER ACTIVITY

44. Between August 2014 and January 2015, a DEA Task Force Officer ("TFO") acted in an undercover capacity (hereinafter "UC") as a "patient" seeking Controlled Substances. Specifically:

45. On or about August 5, 2014, the UC had an initial "patient" visit with **COUCH** at the PPSA Springhill location in Mobile, Alabama. During this initial visit, the UC told a co-conspirator employee that he had previously been self-medicating with oxycodone and Lortab he purchased on the street. Thereafter, during this same office visit, the UC saw **COUCH** for approximately 43 seconds and received a prescription for 90 tablets of Roxicodone 15mg, a Scheduled II Controlled Substance. The prescription was signed by **COUCH**.

46. On or about September 8, 2014, the UC, who was scheduled to have an appointment with **COUCH**, was seen instead by a co-conspirator employee at the Springhill PPSA location in Mobile, Alabama. This employee was not a medical doctor and was not authorized to prescribe or dispense Controlled Substances. During this visit, the UC was provided a prescription for 90 tablets of Roxicodone 15mg, a Schedule II Controlled Substance. The prescription appeared to have been signed by **COUCH**. The UC did not see, nor was he treated by, **COUCH** during this visit.

47. On or about November 5, 2014, the UC, who was scheduled to have an appointment with **COUCH**, was seen instead by a co-conspirator employee at the Springhill PPSA location in Mobile, Alabama. This employee was not a medical doctor and was not authorized to prescribe or dispense Controlled Substances. During this visit, the UC's Roxicodone 15mg prescription, a Schedule II Controlled Substance, was increased to 110 tablets.

This prescription was pre-dated and appeared to have been signed by **COUCH**. In addition, the UC received a second, post-dated prescription for the same drug and quantity. The UC did not see, nor was he treated by, **COUCH** during this visit.

48. On or about January 29, 2015, the UC, who was scheduled to have an appointment with **COUCH**, was seen instead by a co-conspirator employee at the Springhill PPSA location in Mobile, Alabama. This employee was not a medical doctor and was not authorized to prescribe or dispense Controlled Substances. During this visit, the UC received a prescription for 110 tablets of Roxicodone 15mg, a Schedule II Controlled Substance, prior to any physical examination being performed. The prescription appeared to have been signed by **COUCH**. The UC did not see, nor was he treated by, **COUCH** during this visit.

THE PPSA ENTERPRISE

49. The PPSA Enterprise, including its leadership, membership and associates, constituted an enterprise, as defined by Title 18, United States Code, Section 1961(4) (hereinafter "the PPSA Enterprise"), that is, a group of individuals and legal entities associated in fact. The PPSA Enterprise constituted an ongoing organization whose members functioned as a continuing unit for a common purpose of achieving the objectives of the PPSA Enterprise. The PPSA Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

50. Members and associates of the PPSA Enterprise primarily operated the enterprise as a pill mill where numbers of prescriptions for Controlled Substances were written for no legitimate medical purpose or outside the usual course of professional practice. In addition, members and associates of the PPSA Enterprise engaged in medical billing fraud and other criminal violations.

51. Members of the PPSA Enterprise, including the Defendants **COUCH** and **RUAN**,

attempted to insulate themselves through the appearance of legitimate medical practice, which included the use of cursory physical exams, among other means and methods. Many of the prescriptions issued by the Defendants were illegal because they were not issued for a legitimate medical purpose, and not prescribed within the usual course of professional medical practice. The dispensing and distribution of Controlled Substances was undertaken primarily for a profit motive.

52. Members of the PPSA Enterprise also engaged in wide-ranging criminal conduct.

II. CHARGES

COUNT ONE

53. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

THE PPSA ENTERPRISE

54. Beginning at least in or about 2011 and continuing through or about May 20, 2015, the exact dates being unknown, in the Southern District of Alabama and elsewhere, defendants **JOHN PATRICK COUCH, M.D.** and **XIULU RUAN, M.D.**; entities PPSA and C&R Pharmacy; and other individuals known and unknown to the Grand Jury, constituted an Enterprise within the meaning of Title 18, United States Code, Section 1961(4), that is, a group of individuals and entities associated in fact. The PPSA Enterprise constituted an ongoing organization, the members and associates of which functioned as a continuing unit for a common purpose of achieving the objectives of the PPSA Enterprise.

PURPOSES OF THE ENTERPRISE

55. The purpose of the PPSA Enterprise included the following:

A. Providing the PPSA Enterprise and its leaders, members and associates with an expanding base of patients for narcotics distribution;

B. Generating, preserving and protecting the PPSA Enterprise's profits and patient base through acts of, among other things, unlawful drug distribution, healthcare fraud, and kickback violations;

C. Promoting and enhancing the PPSA Enterprise and its leaders, members and associates activities;

D. Enriching the leaders, members and associates of the PPSA Enterprise financially; and

E. Concealing and otherwise protecting the criminal activities of the PPSA Enterprise and its participants from detection and prosecution.

MEANS AND METHODS OF THE ENTERPRISE

56. The manner and methods of the PPSA Enterprise included, but were not limited to, the following:

57. Defendants **COUCH** and **RUAN** co-owned and co-managed PPSA and C&R Pharmacy. Defendants **COUCH** and **RUAN** were aware that individuals would travel from numerous states to Alabama in order to illegally obtain Controlled Substances. Defendants **COUCH** and **RUAN** were aware that individuals requested prescriptions for large quantities of Schedule II, III, and IV Controlled Substances. Defendants **COUCH** and **RUAN** operated the PPSA pain management clinics in order to generate criminal proceeds through the illegal distribution and dispensing of Controlled Substances by means of prescriptions or orders without a legitimate medical purpose and outside the usual course of professional practice. Defendants **COUCH** and **RUAN** conspired to insulate the PPSA Enterprise members from criminal

prosecution by creating the appearance of a legitimate medical practice.

58. The Defendants **RUAN** and **COUCH** frequently prescribed Controlled Substances based on their own financial interests, rather than the legitimate medical needs of the patient. For example, **RUAN** and **COUCH** began prescribing tens of thousands of doses of the Schedule II Controlled Substance Abstral, a TIRF drug only approved by the FDA for breakthrough cancer pain, to non-cancer patients after **RUAN** and **COUCH** each purchased approximately $800,000.00 in stock of Galena Biopharma, Inc., the manufacturer of Abstral. In addition, **RUAN** and **COUCH** would switch patients' prescriptions to drugs, including the Schedule II Controlled Substance Subsys, they were paid to promote, even if the patients' medical needs were being met with their current prescription. Finally, at times, **RUAN** would determine a patient's prescription dose based on C&R Pharmacy's current inventory, as opposed to what a particular patient needed.

59. The Defendants **RUAN** and **COUCH** established a pharmacy, C&R Pharmacy, in order to illegally distribute and dispense Controlled Substances to the individuals receiving prescriptions from the clinics. Defendant **RUAN** also arranged for the dispensing of Controlled Substances directly from one PPSA clinic location to Workers Compensation patients in order to generate large criminal proceeds for himself and **COUCH**.

60. Other co-conspirators, to include but not limited to Justin Palmer, who is not named as a defendant herein, would sign Defendant **COUCH'S** name on prescriptions and other documents in order to expedite the unlawful prescribing and dispensing of Controlled Substances for the PPSA Enterprise.

61. The Defendants **RUAN** and **COUCH** would refrain from individualized and particularized treatment plans for a number of patients in order to expedite the illegal dispensing

of Controlled Substances. The Defendants understood that the majority of individuals seeking Controlled Substances would allege complaints of neck or back pain.

62. Defendant **RUAN** and co-conspirators would typically require that a patient provide a urine sample every 60 to 90 days during the patient's visit at PPSA. These point-of-care urine drug screens (herein after "UDS") would be conducted in order to make the clinic and PPSA's activities appear to be proper and to ensure that the prescription of Controlled Substances appeared to be legitimate.

63. **RUAN**, **COUCH** and co-conspirators did not routinely utilize the UDS analyses for their intended purpose, which was to determine whether a patient was taking the medications they had been prescribed and to ensure that the patients were not taking medications that they had not been prescribed. Rather, **RUAN** and **COUCH** used expensive gas chromatography-mass spectrometer (herein after "GC/MS") testing as a source of additional revenue for PPSA. These tests can be a legitimate part of the practice of pain management. However, **RUAN** and **COUCH** frequently ignored inconsistent GC/MS results, and continued prescribing large quantities of controlled substances to patients regardless of the GC/MS results.

64. In addition, patient services performed by PPSA's physician extenders were fraudulently billed to healthcare benefits programs under the NPI of **COUCH**. This "up-coding" was done because healthcare providers typically paid more in reimbursement for office visits or procedures handled by the physician, as opposed to a physician extender, such as a nurse. The reimbursements for this "up-coding" of services resulted in PPSA and the doctors being paid more per visit by certain healthcare providers than they were entitled to be paid.

65. The Defendants **RUAN** and **COUCH** compensated some of the employee co-conspirators, to include but not limited to Justin Palmer and Bridgette Parker, neither of whom

are named as defendants herein, based on the number of patients seen per day to induce the co-conspirators to see as many patients as possible each day, thereby, generating more money for the Enterprise.

66. The Defendants **RUAN** and **COUCH** and employee co-conspirators, to include but not limited to Justin Palmer and Bridgette Parker, neither of whom are named as defendants herein, would perform a cursory physical examination of the patients in order to insulate the co-conspirators, and in an attempt to justify the drugs being prescribed. The Defendants **RUAN** and **COUCH** and employee co-conspirators would examine individuals for the minimal amount of time possible in order to see the largest number of individuals each day and to generate the largest amount of criminal proceeds for the PPSA Enterprise.

67. **COUCH** and **RUAN** increased their profits by inducing Industrial Pharmacy Management ("IPM"), and later, Comprehensive RX Management ("CRM"), to pay them kickbacks in return for using their medical services, having threatened IPM & CRM with taking their business elsewhere. This inducement was accomplished by **RUAN** soliciting kickbacks for himself and **COUCH**. **RUAN** and **COUCH** increased their profits by receiving these kickbacks in exchange for dispensing Controlled Substances provided by IPM, and later CRM, to workers' compensation patients. Some of the patients were insured through federal healthcare programs. The defendants **RUAN** and **COUCH** were paid an agreed upon monthly amount from IPM, and subsequently from CRM, for dispensing the Controlled Substances. These monthly checks to **RUAN** and **COUCH** were delivered to them in the Southern District of Alabama by an interstate commercial carrier. Defendant **RUAN** requested that monthly kickback checks be made payable to one of his companies and be mailed to his residence in Mobile, Alabama rather than to the PPSA clinics.

68. The defendant **RUAN** would verify, frequently by e-mail, with co-conspirator Christopher Manfuso, who worked for IPM and subsequently owned CRM, and who is not named as a defendant herein, which Controlled Substances resulted in higher reimbursables to PPSA and the defendants **RUAN** and **COUCH**. Based on those conversations between **RUAN** and Manfuso, **RUAN** requested and ordered those Controlled Substances to be delivered to PPSA's dispensary at the PPSA Springhill Avenue location in Mobile, Alabama.

69. Controlled Substances were delivered to the PPSA Springhill Avenue location in Mobile, Alabama, by a commercial interstate carrier, to include but not limited to FedEx, and the United States Postal Service. Thereafter, Defendants **RUAN** and **COUCH** and other members of the conspiracy, would dispense the Controlled Substances based on the false representation that the Controlled Substances, with higher reimbursables, were the medications necessary to treat the Worker's Compensation patients.

70. The agreement between these parties was that **RUAN** and **COUCH** would receive a guaranteed monthly payment and an additional percent of the profits generated by dispensing in house medications, to include Scheduled II and III, Controlled Substances, which had been provided them by IPM, and later, by CRM, to patients.

71. The defendants **COUCH** and **RUAN** set up and maintained an online PPSA account with Blue Cross/Blue Shield ("BC/BS"), and other healthcare providers, so as to electronically submit medical claims and so as to be reimbursed electronically by BC/BS, and other healthcare providers.

72. Specifically, as part of said conspiracy, members of the conspiracy, both known and unknown to the Grand Jury, fraudulently procured electronic payment from healthcare providers, to which they were not entitled. The submission of bills to healthcare providers and

the payment from the healthcare providers caused interstate wire transmissions, to include e-mails, and electronic wire transfers, to be sent to and from the state of Alabama to places outside the state of Alabama, to include the Southern District of Alabama. Members of the conspiracy would also use or cause to be used commercial interstate carriers and the United States Postal Service, and would use or cause to be used interstate wire communications, that is e-mails and telephone calls, to be used for other purposes in furtherance of said scheme and artifice to defraud.

THE CONSPIRACY

73. During at least in or about 2011 and continuing thereafter through at least in or about May 20, 2015, the exact dates being unknown, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

being persons employed by and associated with the PPSA Enterprise, which PPSA Enterprise engaged in, and the activities of which affected, interstate and foreign commerce, did knowingly, willfully and unlawfully combine, conspire, confederate, and agree, together and with each other, and with persons known and unknown to the Grand Jury, to violate Title 18, United States Code, Section 1962(c), that is, to conduct and participate, directly and indirectly, in the conduct of the affairs of the PPSA Enterprise, through a pattern of racketeering activity, as that term is defined in Title 18, United States Code, Sections 1961(1) and (5), consisting of:

THE PATTERN OF RACKETEERING ACTIVITY

74. The pattern of racketeering activity, as defined in Title 18, United States Code, Sections 1961(1) and 1961(5), through which the defendants and their co-conspirators agreed to conduct and participate in the conduct of the affairs of the PPSA Enterprise consisted of:

A. Multiple offenses involving the felonious manufacturing, receiving, concealment, buying, selling or otherwise dealing in Controlled Substances, in violation of Title 21, United States Code, Sections 841(a)(1) and 846; and

B. Multiple acts indictable under Title 18, United States Code, Section 1343 (Relating to Wire Fraud) and Title 18, United States Code, Section 1341 (Relating to Mail Fraud).

75. It was part of the conspiracy that each Defendant agreed that a conspirator would commit at least two acts of racketeering in the conduct of the affairs of the PPSA Enterprise.

76. All in violation of Title 18, United States Code, Section 1962(d).

COUNT TWO

77. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

78. Beginning during, or at least in, 2011, and continuing thereafter through May 20, 2015, in the Southern District of Alabama and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

conspired with each other and with others, both known and unknown to the Grand Jury, to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed, Schedule II Controlled Substances, including, but not limited to: oxycodone (brand names: OxyContin, Roxicodone, Percocet, and Endocet,), oxymorphone (brand name: Opana), hydromorphone (brand names: Exalgo and Dilaudid), and morphine (brand names: MsContin and Avinza), by means of prescriptions, among other means and methods, outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1).

79. All in violation of Title 21, United States Code, Section 846.

COUNT THREE

80. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

81. Beginning during, or at least in, 2011, and continuing thereafter through May 20, 2015, in the Southern District of Alabama and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

conspired with each other and with others, both known and unknown to the Grand Jury, to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed, a Scheduled II Controlled Substance, that is: a mixture and substance containing detectable amount of N–phenyl–N–[1–(2–phenylethyl)–4–piperidinyl] propanamide, which is commonly referred to as fentanyl (brand names: Subsys, Abstral, Fentora, Lazanda, Actiq, and Duragesic), outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1).

82. Because the conspiracy involved more than 40 grams of fentanyl, the penalty provisions of Title 21, United States Code, Section 841(b)(1)(B)(vi) apply.

83. All in violation of Title 21, United States Code, Section 846.

COUNT FOUR

84. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

85. Beginning during, or at least in, 2011, and continuing thereafter through May 20, 2015, in the Southern District of Alabama and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

conspired with each other and with others, both known and unknown to the Grand Jury, to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed, Schedule III Controlled Substances, including, but not limited to: hydrocodone, by means of prescriptions, among other means and methods, outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1).

86. All in violation of Title 21, United States Code, Section 846.

COUNTS FIVE THROUGH SEVEN

87. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

88. On or about the date set forth below, in the Southern District of Alabama, Southern Division, the defendant,

JOHN PATRICK COUCH, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute and dispense a mixture and substance containing a detectable amount of oxycodone, to wit: Roxicodone 15mg, a Schedule II Controlled Substance, to an undercover DEA Task Force Officer for no legitimate medical purpose and outside the usual course of professional practice.

89. The allegations set forth in paragraphs 87–88 above, are hereby realleged and incorporated by reference for each of the following counts, as though fully set forth therein:

Count	Date	Patient	Controlled Substance	Number of Pills	Strength

FIVE	08/05/14	"UC Patient"	Roxicodone	90	15mg
SIX	09/08/14	"UC Patient"	Roxicodone	90	15mg
SEVEN	11/05/14	"UC Patient"	Roxicodone	110	15mg

90. In violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2(a).

COUNTS EIGHT THROUGH TEN

91. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

92. On or about the date set forth below, in the Southern District of Alabama, Southern Division, the defendant,

XIULU RUAN, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute and dispense a mixture and substance containing a detectable amount a Schedule II Controlled Substance, to the patients identified below, for no legitimate medical purpose and outside the usual course of professional practice.

93. The allegations set forth in paragraphs 91–92 above, are hereby realleged and incorporated by reference for each of the following counts, as though fully set forth therein:

Count	Date Prescribed	Patient	Controlled Substance	Number of Pills	Strength
EIGHT	2/26/2015	D.G.	Abstral Subsys Abstral Subsys Oxycontin Norco	32 60 32 60 60 90	400 mcg 400 mcg 400 mcg 400 mcg 40 mg 10 mg

NINE	4/27/2015	K.L.	Fentora Oxycontin Oxycodone	56 60 120	600 mcg 80 mg 15 mg
TEN	7/15/2014	E.G.	Fentora Zohydro ER	112 60	600 mcg 50 mg

94. In violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2(a).

COUNT ELEVEN

95. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

96. On or about November 25, 2014, in the Southern District of Alabama, Southern Division, the defendant,

XIULU RUAN, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute the following Controlled Substance:

> A mixture and substance containing a detectable amount of Oxymorphone, a Schedule II Controlled Substance, under the brand name Opana,

for no legitimate medical purpose, and outside the usual course of professional practice, to an individual identified herein as D.W.

97. In violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2.

98. The use of the prescribed substance resulted in death and serious bodily injury to D.W., thus the penalty provisions set out in Title 21, United States Code, Section 841(b)(1)(C) apply.

COUNT TWELVE

99. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

100. On or about October 10, 2012, in the Southern District of Alabama, Southern Division the defendant,

XIULU RUAN, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute the following Controlled Substance:

> (1) A mixture and substance containing a detectable amount of Morphine Sulfate, a Schedule II Controlled Substance, under the brand name MS-Contin,

for no legitimate medical purpose, and outside the usual course of professional practice, to an individual identified herein as J.B.

101. In violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2.

102. The use of the prescribed substances resulted in death and serious bodily injury to J.B, thus the penalty provisions set out in Title 21, United States Code, Section 841(b)(1)(C) apply.

COUNT THIRTEEN

103. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

104. On or about March 5 and March 11, 2015, in the Southern District of Alabama, Southern Division, the defendant,

JOHN PATRICK COUCH, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute the following Controlled Substances:

> (1) A mixture and substance containing a detectable amount of Oxycodone Hydrochloride, a Schedule II Controlled Substance, under the brand name Roxicodone;
>
> (2) A mixture and substance containing a detectable amount of Oxycodone, a Schedule II Controlled Substance, under the brand name OxyContin,

for no legitimate medical purpose, and outside the usual course of professional practice, to an individual identified herein as K.D.

105. In violation of Title 21, United States Code, Section 841(a)(1), and Title 18, United States Code, Section 2.

106. The use of the prescribed substances resulted in death and serious bodily injury to K.D., thus the penalty provisions set out in Title 21, United States Code, Section 841(b)(1)(E)(i) apply.

COUNT FOURTEEN

107. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

108. On or about March 18 and 31, 2014, in the Southern District of Alabama, Southern Division, the defendant,

JOHN PATRICK COUCH, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, did knowingly, intentionally, and unlawfully distribute the following Controlled Substances:

> (1) A mixture and substance containing a detectable amount of Oxymorphone, a Schedule II Controlled Substance, and

(2) A mixture and substance containing a detectable amount of Morphine Sulfate Instant Release, a Schedule II Controlled Substance.

for no legitimate medical purpose, and outside the usual course of professional practice, to an individual identified herein as P.C.

109. In violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2.

110. The use of the prescribed substances resulted in death and serious bodily injury to P.C., thus the penalty provisions set out in Title 21, United States Code, Section 841(b)(1)(C) apply.

COUNT FIFTEEN

111. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

112. Beginning during, or at least in, 2011, and continuing through May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

did knowingly, willfully, and unlawfully combine, conspire, confederate, and agree with each other, and with others, both known and unknown to the Grand Jury, to commit certain offenses against the United States, to wit:

to knowingly and willfully execute, and attempt to execute a scheme and artifice to defraud a healthcare benefits program, and to obtain, by means of false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, a healthcare benefits program in connection with the delivery of and payment for healthcare benefits, items, and services, in violation of Title 18, United States Code, Section 1347(a).

OBJECTIVE OF THE CONSPIRACY

113. The objective of the conspiracy was to unlawfully increase, through false and fraudulent manners, means, and pretenses, the reimbursements received by PPSA and C&R Pharmacy from private, state, and federal healthcare benefits programs.

MANNER AND MEANS OF THE CONSPIRACY

114. The manner and means used to achieve this objective included, but were not limited to, the following:

A. Billing patients' insurance providers for Controlled Substances that were not prescribed for a legitimate medical purpose or were prescribed outside the usual course of professional practice;

B. Submitting false, fraudulent, and materially misleading medical information to patients' insurance providers for the purpose of getting their insurance providers to pay for extremely dangerous and expensive TIRF drugs;

C. Running and then billing patients' insurance providers for various lab tests, including urine drug screens, for no legitimate medical purpose and outside the usual course of professional practice;

D. Falsely and fraudulently billing patients' insurance providers for office visits using a physician's national provider identifier number, when the physician did not see, treat, or render any service to the patient.

115. All in violation of Title 18, United States Code, Section 1349.

COUNT SIXTEEN

116. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

117. From in or about March 5, 2011, and continuing through in or about May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

did knowingly, willfully, and unlawfully combine, conspire, confederate, and agree together with each other, and with co-conspirators "M.D." and Christopher Manfuso, neither of whom are named defendants herein, and other persons, both known and unknown to the Grand Jury, to commit certain offenses against the United States, to-wit:

> to knowingly and willfully offer, pay, solicit, and receive any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, and in return for purchasing, leasing, ordering, and arranging for or recommending purchasing, leasing, and ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. In violation of Title 42, United States Code, Section 1320a-7b(b).

OBJECTIVE OF THE CONSPIRACY

118. The objective of the conspiracy was for **RUAN** and **COUCH** to unlawfully receive illegal kickbacks as an inducement and in exchange for referrals of workers compensation patients.

MANNER AND MEANS OF THE CONSPIRACY

119. Industrial Pharmaceuticals Management ("IPM"), owned by co-conspirator M.D., was a California-based company that specialized in establishing and managing in-house dispensaries in medical clinics that treated workers compensation ("WC") patients. Once a contract was signed allowing IPM to manage the in-house dispensary, IPM supplied the dispensary with drugs and provided doctors with potential formularies. To induce and in

exchange for doctors' in-house dispensing business, there were times that IPM paid certain doctors large sums of money in the form of monthly "guarantees."

120. In March 2011, **RUAN** and **COUCH** entered into contracts with IPM, whereby IPM agreed to manage a WC dispensary within PPSA. These contracts were signed by co-conspirator M.D. Christopher Manfuso was the regional manager who oversaw the IPM dispensary at PPSA.

121. To induce **RUAN** and **COUCH** to sign these contracts, IPM offered to pay **RUAN** and **COUCH** monthly guaranteed payments of $45,000.00 and $18,000.00, respectively. A second contract between IPM and **RUAN** increased his guarantee to $53,000.00 per month. Once the contracts were signed, these guaranteed payments continued to be made each month in exchange for **RUAN** and **COUCH** referring their WC patients to the IPM dispensary within PPSA.

122. In December 2013, Manfuso left the employment of IPM and formed a new WC dispensary company called Comprehensive RX Management ("CRM"). When he formed CRM, Manfuso purchased some of IPM's customer accounts, including the accounts of **RUAN** and **COUCH**. The kickback payments in exchange for WC patient referrals continued with **RUAN's** payments increasing up to $80,000.00 per month.

123. Between May 24, 2011 and January 21, 2015, IPM and later CRM paid $864,770.41 to **COUCH** and $1,765,132.46 to **RUAN** to induce, and in exchange for, **RUAN** and **COUCH** referring their WC patients to the IPM dispensary.

124. The kickback payments made by IPM, and later CRM, were not paid to PPSA. Rather, the monthly "guarantees" were paid to separate personal and business accounts controlled by **RUAN** and **COUCH**.

125. **RUAN** and **COUCH** received a combined $2,629,902.87, in their personal capacity, as an inducement and in exchange for WC patient referrals.

OVERT ACTS

126. On or about September 20, 2012, **COUCH** received a check numbered 11667, payable to John Patrick Couch, M.D., from IPM, in the amount of $38,543.70.

127. On or about February 25, 2013, **RUAN** received a check numbered 12649, payable to Ruan Companies, LLC, from IPM, in the amount of $53,000.00.

128. On or about September 18, 2013, **COUCH** received a check numbered 13570, payable to Physicians Compounding Solutions, LLC, from IPM, in the amount of $21,860.95.

129. On or about August 15, 2014, **COUCH** received a check number 1280, payable to Physicians Compounding Solutions, LLC, from CRM, in the amount of $33,020.85.

130. On or about November 18, 2014, **RUAN** received a check numbered 1452, payable to Ruan Companies, LLC, from CRM, in the amount of $80,000.00.

131. On or about January 21, 2015, **RUAN** received a check numbered 1555, payable to Ruan Companies, LLC, from CRM, in the amount of $75,000.00.

132. All in violation of Title 18, United States Code, Section 371.

COUNT SEVENTEEN

133. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

134. From in or about August 2012, and continuing through May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

did knowingly, willfully, and unlawfully combine, conspire, confederate, and agree with each

other, with co-conspirator Natalie Perhacs, who is not named as a defendant herein, and with other persons, both known and unknown to the Grand Jury, to commit certain offenses against the United States to- wit:

> to knowingly and willfully offer, pay, solicit, and receive any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, and in return for purchasing, leasing, ordering, and arranging for or recommending purchasing, leasing, and ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. In violation of Title 42, United States Code, Section 1320a-7b(b).

OBJECTIVE OF THE CONSPIRACY

135. The objective of the conspiracy was the unlawful payment to and receipt of illegal kickbacks by **RUAN** and **COUCH** as an inducement and in exchange for their prescribing of the TIRF drug Subsys to patients at PPSA.

MANNER AND MEANS OF THE CONSPIRACY

136. In January 2012, the FDA approved a new TIRF drug under the brand name Subsys. Subsys was manufactured by Insys Therapeutics, Inc.

137. The only FDA-approved indication for Subsys was for the "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Subsys is marketed in single-dose spray bottles in strengths of 100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg.

138. Due to both the extreme dangers and expense of Subsys, many healthcare providers required prior approval before they would reimburse for a patient's Subsys

other, with co-conspirator Natalie Perhacs, who is not named as a defendant herein, and with other persons, both known and unknown to the Grand Jury, to commit certain offenses against the United States to- wit:

> to knowingly and willfully offer, pay, solicit, and receive any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, and in return for purchasing, leasing, ordering, and arranging for or recommending purchasing, leasing, and ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. In violation of Title 42, United States Code, Section 1320a-7b(b).

OBJECTIVE OF THE CONSPIRACY

135. The objective of the conspiracy was the unlawful payment to and receipt of illegal kickbacks by **RUAN** and **COUCH** as an inducement and in exchange for their prescribing of the TIRF drug Subsys to patients at PPSA.

MANNER AND MEANS OF THE CONSPIRACY

136. In January 2012, the FDA approved a new TIRF drug under the brand name Subsys. Subsys was manufactured by Insys Therapeutics, Inc.

137. The only FDA-approved indictation for Subsys was for the "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Subsys is marketed in single-dose spray bottles in strengths of 100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg.

138. Due to both the extreme dangers and expense of Subsys, many healthcare providers required prior approval before they would reimburse for a patient's Subsys

prescription.

139. Starting in or about April 2012, and continuing up to May 20, 2015, **RUAN** and **COUCH** wrote thousands of prescriptions for Subsys, nearly all of which went to PPSA patients who did not have cancer.

140. A vast majority of these prescriptions for Subsys were filled at C&R Pharmacy, which was owned by **RUAN** and **COUCH**.

141. By early 2013, **RUAN** and **COUCH** had become two of the top ten largest volume prescribers of Subsys in the entire nation.

142. In April 2013, Insys Therapeutics hired Natalie Perhacs to be the Subsys drug representative for **RUAN** and **COUCH.** Perhacs's commissions were tied to the amount of Subsys **RUAN** and **COUCH** prescribed to their patients. During the 25–month period between April 2013 and May 2015, Insys Therapeutics paid Perhacs over $700,000.00.

143. One of Perhacs's roles as the representative handling **RUAN** and **COUCH** was to set up speaker engagements during which **RUAN** and **COUCH** were to present information about Subsys to other potential prescribers of the drug. Perhacs attended these speaking engagements on behalf of Insys. However, on many occasions, the speaking engagements were only attended by, **RUAN** and **COUCH,** PPSA employees, and Insys employees.

144. Between August 2012 and May 2015, Insys paid **RUAN** and **COUCH** a combined total in excess of $115,000.00. While this money was ostensibly paid for "speaking fees," it was actually paid to induce, and in exchange for, **RUAN** and **COUCH** prescribing high volumes of Subsys.

OVERT ACTS

145. On or about March 1, 2013, **RUAN** received check number 10479, payable to

Xiulu Ruan, in the amount of $2,400.00.

146. On or about May 9, 2013, **COUCH** received check number 11090, payable to John Patrick Couch, in the amount of $3,200.00.

147. On or about February 13, 2014, **COUCH** received check number 1920, payable to John Patrick Couch 1099, in the amount of $1,600.00.

148. On or about May 1, 2014, **RUAN** received check number 3057, payable to Xiulu Ruan XLR Properties, LLC., in the amount of $6,000.00.

149. On or about October 31, 2014, **COUCH** received check number 5091, payable to John Patrick Couch 1099, in the amount of $3,750.00.

150. On or about November 14, 2014, **RUAN** received check number 5390, payable to Xiulu Ruan XLR Properties, LLC., in the amount of $3,750.00.

151. All in violation of Title 18, United States Code, Section 371.

COUNT EIGHTEEN

152. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

153. From in or about September 2014, and continuing through in or about February 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

did knowingly, willfully, and unlawfully combine, conspire, confederate, and agree with each other, and with other persons, both known and unknown to the Grand Jury, to commit certain offenses against the United States to-wit:

> to knowingly and willfully solicit and receive any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for referring an

individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, and in return for purchasing, leasing, ordering, and arranging for or recommending purchasing, leasing, and ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. In violation of Title 42, United States Code, Section 1320a-7b(b).

OBJECTIVE OF THE CONSPIRACY

154. The objective of the conspiracy was the unlawful receipt of illegal kickbacks by **RUAN** and **COUCH**, through C&R Pharmacy, as an inducement and in exchange for their prescribing of the TIRF drug Abstral to patients at PPSA.

MANNER AND MEANS OF THE CONSPIRACY

155. In January 2011, the FDA approved a new TIRF drug under the brand name Abstral. During the time period alleged in this count, Abstral was manufactured by Galena Biopharma, Inc.

156. The only FDA-approved indication for Abstral was for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain." Abstral was marketed as a dissolvable oral tablet in dosage strengths of 100mcg, 200mcg, 300mcg, 400mcg, 600mcg, and 800mcg.

157. Due to both the extreme dangers and expense of Abstral, many healthcare providers required prior approval before they would reimburse for a patient's Abstral prescription.

158. **RUAN** and **COUCH** began prescribing Abstral in early 2011. However, they did this very sparingly until October 2013.

159. Beginning in the 4th quarter of 2013, **RUAN** and **COUCH** went from prescribing

a few hundred micrograms of Abstral per month to prescribing millions of micrograms of Abstral per month. This meteoric rise in **RUAN** and **COUCH** prescribing Abstral coincided with each doctor purchasing approximately $800,000.00 of stock in Abstral's manufacturer, Galena Biopharma. After buying a combined total of approximately $1,600,000.00 in Galena stock, **RUAN** and **COUCH** quickly became the Number One and Number Two prescribers, respectively, of Abstral in the entire United States.

160. Between the 4th quarter of 2013 though the 4th quarter of 2014, approximately 30% of all Abstral prescriptions written in the entire nation were written by **RUAN** and **COUCH**. **RUAN,** alone, accounted for approximately 1 out of every 5 Abstral prescriptions written during this time period. Nearly all of the prescriptions **RUAN** and **COUCH** wrote for Abstral were written off-label for patients who did not have "underlying persistent cancer pain."

161. Despite leading the nation in Abstral prescribing in 2014, **RUAN** and **COUCH** drastically cut back the number of prescriptions they wrote between April and September 2014. This dip from over 2,000,000 micrograms per month to less than 1,000,000 coincided with a dramatic drop in the price of Galena stock.

162. On or about October 1, 2014, after four straight months in which neither **RUAN** nor **COUCH** prescribed more than 1,000,000 micrograms of Abstral, Galena entered into a rebate agreement with C&R Pharmacy whereby, Galena would pay a scaled rebate based on the volume of Abstral purchased by C&R Pharmacy. C&R Pharmacy was owned by **RUAN** and **COUCH**, and almost exclusively filled prescriptions written by **RUAN** and **COUCH**.

163. Immediately after entering into the rebate agreement, **RUAN** and **COUCH** resumed prescribing large volumes of Abstral.

164. Thereafter, in February 2015, C&R Pharmacy received a payment of $97,924.00

as a rebate based on the volume of Abstral purchased by the pharmacy.

OVERT ACTS

165. On or about October 1, 2014, C&R Pharmacy, which is jointly owned by **RUAN** and **COUCH,** entered into a rebate agreement with Galena Biopharma.

166. On or about February 18, 2015, Galena Biopharma executed a wire transfer in the amount of $97,924.00 to the C&R Pharmacy bank account ending in x7003.

167. All in violation of Title 18, United States Code, Section 371.

COUNT NINETEEN

168. The Grand Jury incorporates number paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

169. From on or about January 1, 2011 through in or about May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendants,

JOHN PATRICK COUCH, M.D. and
XIULU RUAN, M.D.,

did conspire with one another and others, both known and unknown to the Grand Jury, including co-conspirators Natalie Perhacs, Justin Thomas Palmer, and Bridgette Parker, none of whom are named as defendants herein, to execute and attempt to execute a scheme and artifice to defraud, described below, and for obtaining money and property by means of false and fraudulent pretenses, representations, and promises, to wit: (1) Wire Fraud in violation of Title 18, United States Code, Section 1343, and (2) Mail Fraud in violation of Title 18, United States Code, Section 1341.

OBJECTIVE OF THE CONSPIRACY

170. The objects of the conspiracy, among others, were to procure payments from

healthcare providers to which PPSA and the defendants were not entitled by false representations; and to procure payments for dispensing Controlled Substances to Workers Compensation patients, which Controlled Substances were selected because of the higher reimbursable to the defendants rather than for the needs of the patient.

MANNER AND MEANS OF THE CONSPIRACY

171. The defendants **COUCH** and **RUAN** set up and maintained an online PPSA account with Blue Cross/Blue Shield ("BC/BS"), and other healthcare providers, so as to electronically submit medical claims and so as to be reimbursed electronically by BC/BS, and other healthcare providers.

172. Members of the conspiracy, both known and unknown to the Grand Jury, fraudulently submitted claims for patient visits with **COUCH** or **RUAN**, which had, in fact, been patient visits with a PPSA Physician Extender, rather than a doctor. The reimbursements for this "up-coding" of services resulted in PPSA being paid approximately 30% more per doctor visit by BCBS, and other healthcare providers, than the payment to which PPSA and the doctors were entitled.

173. **RUAN** would verify by e-mail with co-conspirator Manfuso, who is not named as a defendant herein; who worked for IPM and subsequently owned CRM, and who did not live in the State of Alabama, which Controlled Substances resulted in higher reimbursables to PPSA and the defendants and, based on that fact, **RUAN** requested and ordered those Controlled Substances to be delivered to PPSA's dispensary at the PPSA Springhill Avenue location in Mobile, Alabama.

174. Controlled Substances were delivered to the PPSA Springhill Avenue location in Mobile, Alabama, by a commercial interstate carrier, to include but not limited to FedEx, and the

United States Postal Service. Thereafter, **RUAN** and **COUCH** and other members of the conspiracy, would dispense the Controlled Substances based on the false representation that the Controlled Substances, with higher reimbursables, were the medications necessary to treat the Worker's Compensation patient.

175. **RUAN** and **COUCH** were paid an agreed upon monthly amount from IPM, and subsequently from CRM, for dispensing the Controlled Substances. These monthly checks were delivered to **RUAN** and **COUCH** by an interstate commercial carrier.

176. In carrying out their scheme, members of the conspiracy would use or cause to be used commercial interstate carriers and the United States Postal Service, and would use or cause to be used interstate wire communications, that is e-mails and telephone calls, to be used for other purposes in furtherance of said scheme and artifice to defraud.

177. Specifically, as part of said conspiracy, members of the conspiracy, both known and unknown to the Grand Jury, fraudulently procured electronic payment from BCBS, and other healthcare providers, to which they were not entitled. The submission of bills to BCBS and the payment from BCBS caused wire transmissions, to include e-mails, and electronic wire transfers, to be sent to and from the state of Alabama to places outside the state of Alabama, to include the Southern District of Alabama.

178. Perhacs and others aided **RUAN** and **COUCH** in submitting false, fraudulent, and materially misleading documentation to patients' insurance providers in an effort to get reimbursed for the off-label prescribing of dangerous and expensive TIRF cancer drugs.

179. All in violation of Title 18, United States Code, Section 1349.

COUNT TWENTY

180. The Grand Jury incorporates numbered paragraphs 1–52 of this Second

Superseding Indictment as if fully set forth herein.

181. From on or about or about March 5, 2011, through in or about May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendant,

XIULU RUAN, M.D.,

aided and abetted by Christopher Manfuso, who is not named as a defendant herein, and by others, both known and unknown to the Grand Jury, did knowingly conspire, confederate, and agree with other persons, both known and unknown to the Grand Jury, to commit an offense against the United States, in violation of Title 18, United States Code, Section 1957, to wit: to knowingly engage and attempt to engage, in monetary transactions by, through and to a financial institution, affecting interstate and foreign commerce, in criminally derived property of a value greater than $10,000, that is, among other means and methods, transferring funds from bank accounts to other individuals by wire transfers, such property having been derived from a specified unlawful activity, that is, violations of and conspiracies to violate Title 18, United States Code, Section 1349 (conspiracy to commit healthcare fraud), and Section 371 (conspiracy to violate the Anti-Kickback Statute); and Title 21, United States Code, Section 846 (conspiracy to distribute Controlled Substances).

182. In violation of Title 18, United States Code, Section 1956(h).

COUNTS TWENTY-ONE AND TWENTY-TWO

183. The Grand Jury incorporates numbered paragraphs 1–52 of this Second Superseding Indictment as if fully set forth herein.

184. On or about the dates set forth below, in the Southern District of Alabama, Southern Division, the defendant,

XIULU RUAN, M.D.,

aided and abetted by others, both known and unknown to the Grand Jury, knowingly engaged and attempted to engage in the following monetary transactions by, through and to a financial institution, affecting interstate or foreign commerce, in criminally derived property of a value greater than $10,000; that is the deposit, withdrawal, transfer, and exchange of U.S. currency, funds, or monetary instruments, such property having been derived from a specified unlawful activity, namely violations of and conspiracies to violate Title 18, United States Code, Section 1349(conspiracy to commit healthcare fraud), and 371(conspiracy to violate the anti-kickback statutes); and Title 21, United States Code, Section 846 (conspiracy to distribute Controlled Substances).

185. With respect to Counts Twenty-One and Twenty-Two set forth below, **RUAN** caused funds to be wired from the bank accounts identified below to the individuals and the accounts listed in the "Recipient" column.

Count	Date	Originating Financial Institution and Account	Recipient	Amount
TWENTY-ONE	08/14/2014	Wire transfer from State Bank & Trust Acct. ending 5553, in the name of XLR Exotic Autos LLC	JPMorgan Chase Bank, Acct. ending 9273, Dallas, Texas	$124,355.87
TWENTY-TWO	09/26/2014	Wire transfer from State Bank & Trust Acct. ending 5553, in the name of XLR Exotic Autos LLC	Comerica Bank Acct. # ending 1629, San Diego, California	$110,000.00

186. All in violation of Title 18, United States Code, Section 1957 and 2(a).

FORFEITURE NOTICES

Pursuant to Rule 32.2(a), Fed. R. Crim. P., the allegations contained in Counts One through Twenty-Two of this Second Superseding Indictment are hereby repeated, realleged, and incorporated by reference herein as though fully set forth at length for the purpose of alleging forfeiture.

RACKETEERING FORFEITURE (COUNT ONE)
(RICO CONSPIRACY)

The defendants, **JOHN PATRICK COUCH** and **XIULU RUAN**, are hereby notified that, upon conviction of the violation of Title 18, United States Code, Section 1962, as charged in Count One of this Second Superseding Indictment, the defendants shall forfeit, pursuant to Title 18, United States Code, Section 1963:

a) All interests acquired and maintained in violation of Title 18, United States Code, Section 1962;

b) All interests in, securities of, claims against, and property and contractual rights of any kind affording a source of influence over, the enterprise named and described herein which the defendant established, operated, controlled, conducted, and participated in the conduct of, in violation of Title 18, United States Code, Section 1962; and

c) All property constituting and derived from proceeds obtained, directly and indirectly, from racketeering activity in violation of Title 18, United States Code, Section 1962.

The property subject to forfeiture to the United States pursuant to Title 18, United States Code, Section 1963(a)(1), (a)(2)(A) – (D), (a)(3), and Title 21, United States Code, Section 853(a)(3), includes, but is not limited to, the following assets:

A. **XIULU RUAN's** Alabama Medical License, number MD25262;

B. **JOHN PATRICK COUCH's** Alabama Medical License, number MD20444;

C. **JOHN PATRICK COUCH's** Georgia Medical License, number 42552;

D. **JOHN PATRICK COUCH's** California Medical License, number 82209;

E. A sum of money in the amount of at least $40,000,000.00 in United States currency, representing the total amount of proceeds obtained by the defendants, as a result of their violation of Title 18, United States Code, Section 1962;

F. The contents of the accounts and funds associated with PPSA and C&R Pharmacy as listed on Page 49.

G. The contents of the accounts associated with **RUAN** as listed on Page 49-50.

H. The contents of the accounts associated with **COUCH** as listed on Page 49-50.

I. The vehicles associated with **RUAN,** as listed on Page 50.

J. The vehicles associated with **COUCH,** as listed on Page 50.

K. The real property associated with **RUAN,** as listed on Page 51.

L. The real property associated with **COUCH,** as listed on Page 51.

All pursuant to Title 18, United States Code, Sections 1963(a)(1), (a)(2)(A)–(D), and (a)(3), and Title 21, United States Code, Section 853(a)(3).

CONSPIRACY TO DISTRIBUTE AND DISPENSE FORFEITURE (COUNTS TWO THROUGH FOUR) AND DISTRIBUTION OF A CONTROLLED SUBSTANCE (COUNTS FIVE THROUGH FOURTEEN)

The allegations contained in Counts Two through Fourteen of this Second Superseding Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 21, United States Code, Section 853(a)(1) and (a)(2).

Upon conviction of an offense as set forth in Counts Two through Fourteen of this Second Superseding Indictment, the defendants **JOHN PATRICK COUCH** and **XIULU RUAN** shall forfeit to the United States of America, pursuant to Title 21, United States Code, Section 853(a)(1) and (a)(2), any property, real or personal, which constitutes or is derived from any proceeds the defendants **COUCH** and **RUAN,** obtained, directly or indirectly, as the result of such violation(s), and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation(s). The property to be forfeited includes, **but is not limited to**, the following:

A. **XIULU RUAN's** Alabama Medical License, number MD25262;

B. **JOHN PATRICK COUCH's** Alabama Medical License, number MD20444;

C. **JOHN PATRICK COUCH's** Georgia Medical License, number 42552;

D. **JOHN PATRICK COUCH's** California Medical License, number 82209;

E. A money judgment against **JOHN PATRICK COUCH** and **XIULU RUAN** representing a sum of money equal to the proceeds the defendants obtained, directly or indirectly, as a result of a violation of Title 21, U.S.C. § 846.

F. The contents of the accounts associated with PPSA and C&R Pharmacy, as listed

on Page 49.

G. The contents of the accounts associated with **RUAN,** as listed on Page 49-50.

H. The contents of the accounts associated with **COUCH,** as listed on Page 49-50.

I. The vehicles associated with **RUAN,** as listed on Page 50.

J. The vehicles associated with **COUCH,** as listed on Page 50.

K. The real property associated with **RUAN,** as listed on Page 51.

L. The real property associated with **COUCH,** as listed on Page 51.

All pursuant to Title 21, United States Code, Sections 853(a)(1) and (a)(2).

CONSPIRACY TO VIOLATE ANTI-KICKBACK STATUTE FORFEITURE (COUNTS SIXTEEN THROUGH EIGHTEEN)

The allegations contained in Counts Sixteen through Eighteen are hereby realleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

Upon conviction of the offense in violation of Title 18, United States Code, Section 371 set forth in Count Sixteen, Seventeen, or Eighteen, of this Second Superseding Indictment, the defendants, **JOHN PATRICK COUCH** and **XIULU RUAN** shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived, from proceeds traceable to a violation of an offense constituting specified unlawful activity, including an act or activity constituting an offense involving a Federal healthcare offense under Title 18, United States Code, Section 1956(c)(7)(F), or a conspiracy to commit such an offense. The property to be forfeited includes, but is not limited to, the following:

A. A money judgment against **COUCH** and **RUAN** representing a sum of money equal to the proceeds the defendants obtained as a result of such, or proceeds traceable to such violation.

B. The contents of the accounts associated with PPSA and C&R Pharmacy, as listed

on Page 49.

C. The contents of the accounts associated with **RUAN,** as listed on Page 49-50.

D. The contents of the accounts associated with **COUCH,** as listed on Page 49-50.

E. The vehicles associated with **RUAN,** as listed on Page 50.

F. The vehicles associated with **COUCH,** as listed on Page 50.

G. The real property associated with **RUAN,** as listed on Page 51.

H. The real property associated with **COUCH,** as listed on Page 51.

All pursuant to the provisions of Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

CONSPIRACY TO COMMIT HEALTH CARE FRAUD FORFEITURE (COUNT FIFTEEN), AND CONSPIRACY TO COMMIT WIRE AND MAIL FRAUD FORFEITURE (COUNT NINETEEN)

The allegations contained in Counts Fifteen and Nineteen of this Second Superseding Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeiture. Pursuant to the provisions of Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), if convicted of the offenses set forth in Count Fifteen or Count Nineteen, defendants **JOHN PATRICK COUCH** and **XIULU RUAN** shall forfeit property, real or personal, which constitutes or is derived from proceeds traceable to the offense, or a conspiracy to commit such offense. The property to be forfeited includes, **but is not limited to**, the following:

A. A money judgment against **JOHN PATRICK COUCH** and **XIULU RUAN** representing a sum of money equal to the proceeds the defendants obtained, directly or indirectly, as a result of a violation of Title 18, U.S.C. § 1349.

B. The contents of the accounts associated with PPSA and C&R Pharmacy, as listed on Page 49.

C The contents of the accounts associated with **RUAN,** as listed on Page 49-50.

D. The contents of the accounts associated with **COUCH,** as listed on Page 49-50.

E. The vehicles associated with **XIULU RUAN,** as listed on Page 50.

F. The vehicles associated with **COUCH,** as listed on Page 50.

G. The real property associated with **RUAN,** as listed on Page 51.

H. The real property associated with **COUCH,** as listed on Page 51.

All pursuant to the provisions of Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

CONSPIRACY TO COMMIT MONETARY TRANSACTIONS IN PROPERTY DERIVED FROM SPECIFIED UNLAWFUL ACTIVITY FORFEITURE (COUNT TWENTY); AND MONEY LAUNDERING FORFEITURE (COUNTS TWENTY-ONE AND TWENTY-TWO)

Pursuant to Title 18, United States Code, Section 982(a)(1), if defendant **XIULU RUAN** is convicted of Count Twenty or Count Twenty-One or Twenty-Two, he shall forfeit to the United States all property, real or personal, involved in such offense(s) and all property traceable to such property.

The Property to be forfeited includes, but is not limited to, the following:

A. A money judgment against **RUAN**, representing a sum of money equal to all property, real or personal, involved in such offense(s), and all property traceable to such property.

B. The contents of the accounts associated with PPSA and C&R Pharmacy, as listed on Page 49.

C. The contents of the accounts associated with **RUAN,** as listed on Page 50.

D. The vehicles associated with **RUAN,** as listed on Page 51.

E. The real property associated with **RUAN,** as listed on Page 51.

All pursuant to Title 18, United States Code, Section 982(a)(1).

SUBSTITUTE ASSETS

If any of the property described above as being subject to forfeiture, as a result of any act or omission of the defendants, **JOHN PATRICK COUCH** and **XIULU RUAN,**

(a) cannot be located upon the exercise of due diligence;
(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 18, United States Code, Section 1963(m), and Section 982(b)(1), Title 21, United States Code, Section 853(p), as incorporated by 28 U.S.C. § 2461, and Rule 32.2 Fed. R. Crim. P., to seek forfeiture of any other property of said defendants up to the value of the forfeitable property described above.

A TRUE BILL

[redacted]

FOREMAN, UNITED STATES GRAND JURY
SOUTHERN DISTRICT OF ALABAMA

KENYEN R. BROWN
UNITED STATES ATTORNEY

By:

DEBORAH A. GRIFFIN
Assistant United States Attorney

CHRISTOPHER J. BODNAR
Assistant United States Attorney

VICKI M. DAVIS
Assistant United States Attorney
Chief, Criminal Division

APRIL 2016

The accounts and funds associated with PPSA and C&R Pharmacy:

1. Wells Fargo account ending in x6971, in the name of PPSA;
2. Wells Fargo account ending x1719, in the name of C&R, L.L.C.;
3. Wells Fargo account ending x7003, in the name of C&R Pharmacy, L.L.C.;
4. $25,595.71 from JPMorganChase check ending 2682, payable to C&R Pharmacy; and
5. $175,773.13 from Bank of America account ending 7563, payable to C&R Pharmacy.

The bank and financial accounts associated with RUAN:

1. State Bank & Trust (hereinafter "SB&T) account ending in x5553, in the name of XLR Exotic Autos, L.L.C.;
2. SB&T account ending in x5264, in the name of Ruan Companies, L.L.C;
3. SB&T account ending in x6197 in the name of Xiulu Ruan;
4. Wells Fargo account ending in x1921, in the name of XLR Properties, L.L.C.;
5. Wells Fargo account ending in x1212, in the name of Physicians Weight Loss and Wellness, L.L.C.;
6. Community Bank account ending in x9013, in the name of Xiulu Ruan;
7. Capital One Sharebuilder Investment Account ending in x6197-01 in Ruan's name;
8. Voya Financial 401K account plan ending in x7645 in Ruan's name;
9. College Counts 529 Fund, accounts ending in x3712
10. College Counts 529 Fund, accounts ending in x3713.

The contents of the following accounts associated with COUCH:

1. Wells Fargo account ending in x0015, in Couch's name;
2. Wells Fargo account ending in x6997, in the name of Physician's Compounding Solutions, L.L.C.;
3. Wells Fargo Account ending in x9824, in Couch's name;
4. Wells Fargo account ending in x6989, in the name of JPC Properties, L.L.C.;
5. Trustmark account ending in x0135, in Couch's name;
6. & 7. E-Trade Investment accounts ending in x4755 and x8497;
8. Voya Financial 401K account plan # ending in x7645;

9. & 10. Allianz Annuity accounts ending in x6369 and x5389;

11. – 13. College Counts 529 Fund, accounts ending in x2423, x8641 and X2406, all owned by Couch.

The following vehicles associated with RUAN:

1. Aston Martin DB9 Volante, VIN #SCFAB02AX6GB04617;
2. Audi R8 Spyder VIN #WUATNAFG2BN002379
3. 2007 Bentley Continental GT, VIN #SCBDR33W47C048251;
4. 1987 BMW M6, VIN #WBAEE1400H2560721;
5. Ferrari F430 Convertible, VIN #ZFFEW59A070156841;
6. Ferrari 599 GTB, VIN #ZFFFC60A270150619;
7. 1994 Lamborghini Diablo, VIN #ZA9DU07P2RLA12227;
8. 2008 Lamborghini, VIN #ZHWBU47M78LA02880;
9. 2005 Mercedes SLR, VIN #WDDAJ76E45M000070;
10. 2011 Mercedes Model SLS AMG, VIN #WDDRJ7HA2BA002474;
11. 2013 Mercedes SLS AMG GT, VIN #WDDRK7JA0DA010048;
12. Shelby Series 1, VIN #5CXSA1816XL000159;
13. Spyker C8 Laviolette VIN #XL9BA11G69Z363202;
14. 2005 Bently Armage (VIN #SCBLC43FX5CX10639);
15. 2005 Bentley Continental GT (VIN SCBCR63W65C024205);
16. 2006 Saleen S7 (VIN 1S9SB18126S000074);
17. 2007 Porsche 911 GT3 (VINWP0AC29997S792687);
18. 2005 Porsche 9TC (VIN WP0CB29965S675240)

The following vehicles associated with COUCH:

1. 2008 Cadillac Escalade, VIN 1GYFK66848R221963;
2. 2013 Maserati, VIN ZAM45VLA3D0072574;
3. 2015 Porsche 911, VIN #WP0BB2A96FS135380;
4. 2006 Porsche 911 Cabriolet (VIN WP0CB299X6S765878)
5. 1969 Chevrolet Corvette Sting Ray (VIN 194379S707748)

The following real property associated with RUAN:

1. 2800 Churchbell Ct. Mobile, Alabama;
2. 1323 Leroy Stevens Road, Mobile, Alabama, 36695 (Mobile County), (Parcel number R022707253000005.002), and which is more particularly described as: Lot 2 Byrum Family Division Map Book 129 Page 35.

The following real property associated with COUCH:

1. 319 Woodbridge Drive Daphne, Alabama;
2. Unit #7, 25040 Perdido Beach Blvd Orange Beach, Alabama;
3. Unit C-804, 28105 Perdido Beach Blvd Orange Beach, Alabama.

J

PENALTY PAGE

CASE STYLE:	**UNITED STATES v. JOHN PATRICK COUCH, et.al.**
DEFENDANTS:	**JOHN PATRICK COUCH (COUNTS 1 - 7, 13 & 14, 15 - 19)** **XIULU RUAN (COUNTS 1 - 4, 8 – 12, 15 - 22)**
USAO NO:	**13R00521**
AUSAs:	**Deborah A. Griffin and Christopher Bodnar**
CODE VIOLATIONS:	
COUNT 1:	**18 U.S.C. §1962(d), RICO Conspiracy**
COUNTS 2 - 4:	**21 U.S.C. § 846, Drug Conspiracy**
COUNTS 5-14:	**21 U.S.C. § 841(a)(1), Distribution of a Controlled Substance**
COUNT 15:	**18 U.S.C. § 1349, Healthcare Fraud Conspiracy**
COUNTS 16-18:	**18 U.S.C. § 371, Conspiracy to Violate Anti-Kickback Statute**
COUNT 19:	**18 U.S.C. § 1349, Wire and Mail Fraud Conspiracy**
COUNT 20:	**18 U.S.C. § 1956(h), Conspiracy to Commit Money Laundering**
COUNTS 21 & 22:	**18 U.S.C. § 1957, Money Laundering**
PENALTIES:	
COUNTS 1, 2, 4–10, & 19:	**20 yrs/$250,000/5 yrs SRT/$100 SA**
COUNT 3:	**5 yrs to 40 yrs/$2,000,000/5 yrs SRT/$100 SA**
COUNTS 11-14:	**20 yrs to life/$10,000,000/5 yrs SRT/$100 SA**
COUNTS 15, 20 - 22:	**10 yrs/$250,000/3 yrs SRT/$100 SA**
COUNTS 16 - 18:	**5 yrs/$250,000/3 yrs SRT/$100 SA**

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	)	**Criminal No. 15-00088**
	)	
v.	)	
	)	
JOHN PATRICK COUCH, M.D. and,	)	
XIULU RUAN, M.D.	)	
	)	

NOTICE TO THE COURT

Comes now the United States of America, by and through Kenyen R. Brown, the United States Attorney for the Southern District of Alabama, and Assistant United States Attorney Deborah A. Griffin, and in accordance with Criminal L.R. 7. provides the following brief statement describing the differences between the superseding and the second superseding charges:

1. Counts Three and Four are new, as are Counts Eight through Fourteen. Counts Seventeen and Eighteen are also news.

Respectfully submitted this the 28th day of April, 2016.

KENYEN R. BROWN
UNITED STATES ATTORNEY
by:

/s/ Deborah A. Griffin
Deborah A. Griffin (GRIFD9200)
Assistant United States Attorney
63 S. Royal Street, Suite 600
Mobile, Alabama 36602
Telephone: (251) 441-5845

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
vs.	)	**CRIMINAL NO. 15-00088-CG**
	)	
JOHN PATRICK COUCH, M.D.,	)	
	)	
Defendant.	)	

VERDICTS

WE, THE JURY, FIND THE DEFENDANT, JOHN PATRICK COUCH, M.D.,

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT ONE.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT TWO.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT THREE.

If, and only if you find the defendant guilty of Count Three, you must unanimously agree on whether the weight of the substance dispensed, Fentanyl, exceeded 40 grams or was 40 grams or below. Check the amount unanimously found:

✓ More than 40 grams of Fentanyl were involved in the offense.

_____ 40 grams or less of Fentanyl were involved in the offense.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT FOUR.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT FIVE.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT SIX.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT SEVEN.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT THIRTEEN.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT FOURTEEN.

GUILTY / ~~**NOT GUILTY**~~ AS CHARGED IN COUNT FIFTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT SIXTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT SEVENTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT NINETEEN.

FOREPERSON

23 Feb 17

DATE

FILED IN OPEN COURT THIS 23rd DAY

OF February, 2017.

CHARLES R. DIARD, JR., CLERK

By _____

DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
vs.	)	**CRIMINAL NO. 15-00088-CG**
	)	
XIULU RUAN, M.D.,	)	
	)	
Defendant.	)	

VERDICTS

WE, THE JURY, FIND THE DEFENDANT, XIULU RUAN, M.D.,

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT ONE.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT TWO.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT THREE.

If, and only if you find the defendant guilty of Count Three, you must unanimously agree on whether the weight of the substance dispensed, Fentanyl, exceeded 40 grams or was 40 grams or below. Check the amount unanimously found:

✓ More than 40 grams of Fentanyl were involved in the offense.

_____ 40 grams or less of Fentanyl were involved in the offense.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT FOUR.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT EIGHT.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT NINE.

~~GUILTY~~ NOT GUILTY AS CHARGED IN COUNT TEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT ELEVEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT TWELVE.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT FIFTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT SIXTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT SEVENTEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT NINETEEN.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT TWENTY.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT TWENTY-ONE.

GUILTY ~~NOT GUILTY~~ AS CHARGED IN COUNT TWENTY-TWO.

FOREPERSON

23 Feb 17

DATE

FILED IN OPEN COURT THIS 23rd DAY

OF February, 2017.

CHARLES R. DIARD, JR., CLERK

By

DEPUTY CLERK